



Pharmaceutical Manufacturing Statutory and Regulatory Summaries



**EPA Office of Compliance
Chemical Industry Branch**



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Background: The pharmaceutical manufacturing industry is subject to numerous Federal regulations that have been enacted to protect human health and the environment. A complex web of requirements results from the fact that little correlation exists among regulations that target the same medium or activity. Industrial facilities are responsible for understanding and complying with these requirements. Historically, EPA has relied on a command and control approach to regulate industrial facilities, but now is combining its traditional method with innovative compliance assessment techniques such as self-assessments and facility management systems.

Many industrial facilities have found that using a complete facility Environmental Management System (EMS) approach uncovers cost effective solutions for tackling all the requirements as a whole instead of as individual components. In line with this discovery, EPA is encouraging self-assessments using a complete facility EMS approach to evaluate compliance with environmental regulations. A facility's drive to identify cheaper, more effective ways to achieve compliance is consistent with EPA's mission of clarifying and simplifying environmental regulatory control.

Purpose of document: This guide is a resource on Federal environmental regulations for pharmaceutical manufacturing facilities. This manual identifies and clarifies industry-specific regulatory information necessary to conduct a self-assessment. This document describes portions of environmental statutes that may apply to the pharmaceutical manufacturing industry and summarizes regulatory requirements of each (including applicability, exemptions, monitoring, record keeping, and reporting requirements).

Approach: The statutes are discussed in the following sections:

- **Clean Air Act (CAA):** Clean Air Act Titles I, III, V, and VI are summarized in this section. Topics include NAAQS, NESHAPs, MACTs, permitting, chemical accident protection, and stratospheric ozone protection. This appendix also includes a section on assessment considerations that should be evaluated during the on-site facility assessment. Regulatory summaries are provided for performance standards, national emission standards, provisions for prevention of chemical accidents, and protection of stratospheric ozone.
- **Safe Drinking Water Act (SDWA):** This section describes the public water system program, underground injection control program, considerations for assessors, and regulatory requirements. Detailed descriptions of the regulatory requirements include national primary and secondary drinking water regulations which may be applicable to facilities that produce their own potable water and the underground injection control program.

- **Resource Conservation and Recovery Act (RCRA):** This section delineates the requirements for generation, transportation, treatment, storage, and disposal of hazardous waste. Land disposal restrictions and underground storage tank regulations are discussed, as are specific RCRA assessment considerations. RCRA legislation summarized for pharmaceutical manufacturers includes classification of generators; requirements for hazardous waste generators and transporters; regulations for hazardous waste treatment, storage, and disposal; and restrictions on land disposal and underground storage tanks.
- **Emergency Planning and Community Right-to-Know Act (EPCRA):** The EPCRA section describes four regulatory programs applicable to pharmaceutical manufacturers: hazardous substance notification, emergency planning and notification, hazardous chemical reporting to the community, and toxic chemical release inventory. The section also suggests key areas to evaluate during compliance assessments. Regulatory summaries are included for the following: designation, notification, and reportable quantities of hazardous substances; emergency planning and notification; and reporting of hazardous chemicals and toxic chemical releases.
- **Clean Water Act (CWA):** This section includes effluent limit guidelines, categorical pretreatment standards, NPDES and pretreatment programs, effluent trading, spills and pollution prevention of oil and hazardous substances, and reportable quantities of hazardous substances. This chapter also includes a section on assessment considerations and summaries of regulations pertaining to pretreatment and discharge of effluent, discharge and pollution prevention of oil, and designation of hazardous substances and reportable quantities.

This manual may not include all the Federal environmental regulations that a pharmaceutical manufacturer must comply with, but it should serve as a starting point. Site assessors should be aware that, in many instances, State or local regulations may be more stringent than Federal requirements. Also, site-specific Federal, State, or local permits may contain additional requirements beyond those specified in the regulations. As such, part of a facility's EMS should be to check Federal, State and local regulations regularly and keep abreast of pending legislation that may impact the facility.

DISCLAIMER

This document is intended as an aid to compliance with federal regulatory requirements. The document does not, however, substitute for EPA's regulations, nor is it a regulation itself. Thus, it cannot impose legally binding requirements on EPA, States, or the regulated community. Because circumstances vary, this document may not apply to a particular situation based on the circumstances, and facilities may be subject to requirements that are different from or in addition to those described in this document. EPA may change this guidance in the future, as appropriate.

NOTE TO USERS OF THIS DOCUMENT

This document contains internal hyperlinks. Internal links, noted with magenta text, link the reader to the applicable section, figure, appendix, etc. being referenced. In addition, selecting the bookmark option from the top menu in the Adobe Acrobat Reader provides the user with a point and click table of contents to the first page of each statute to simplify navigation in the document.

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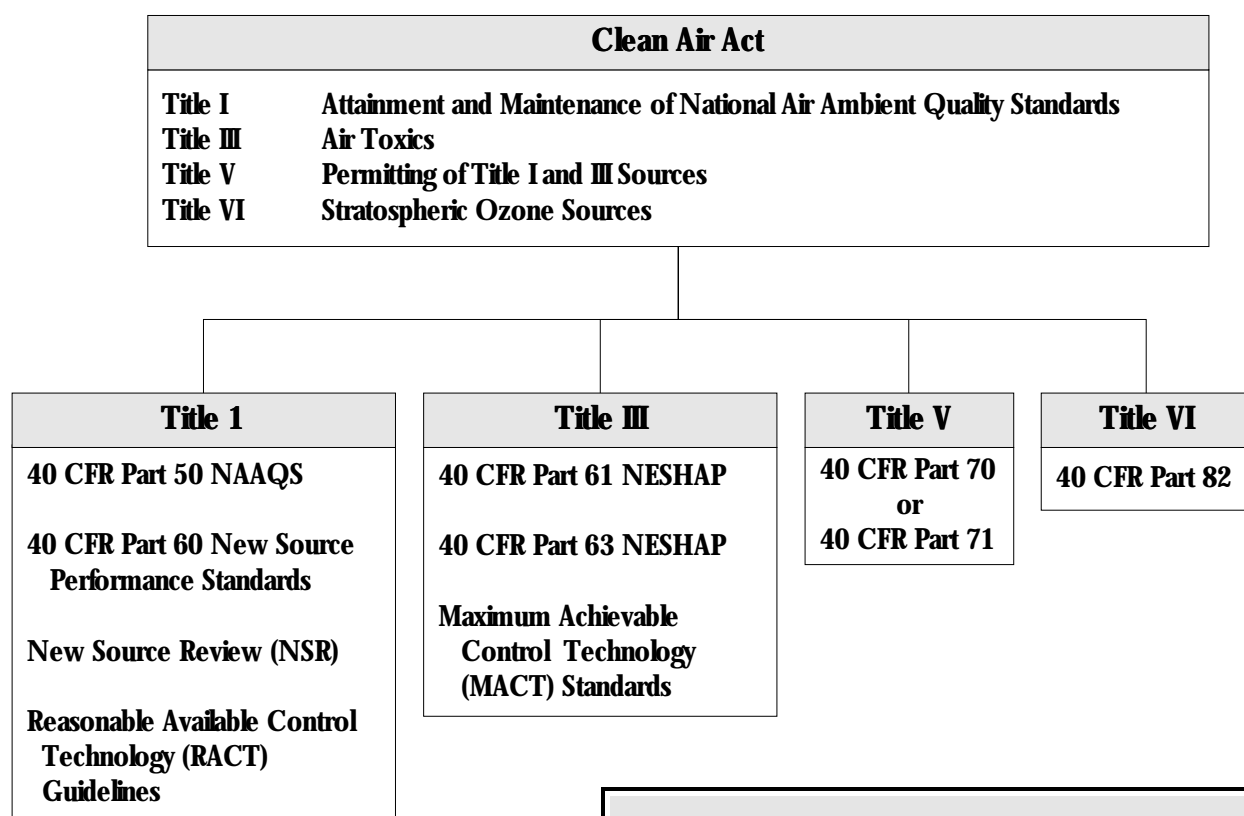
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Clean Air Act (CAA)

The Clean Air Act (CAA), with its 1990 amendments, sets the framework for air pollution control as it affects the pharmaceutical manufacturing industry. This framework has several elements based upon individual titles in the CAA. The applicable CAA titles and the regulations and guidelines developed pursuant to the CAA are illustrated in Exhibit CAA-1 and are discussed below.

Exhibit C



Several portions of Title I of the CAA address requirements for the attainment and maintenance of National Ambient Air Quality Standards (NAAQS). The central components of the regulatory scheme of the Act may be said to include the following:

Clean Air Act

National Primary and Secondary Ambient Air Quality Standards	CAA-2
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- ▶ Section 107 pertaining to Air Quality Control Regions
- ▶ Section 109 pertaining to National Ambient Air Quality Standards
- ▶ Section 110 pertaining to State Implementation Plans
- ▶ Section 111 pertaining to New Source Performance Standards
- ▶ Section 112 pertaining to National Emission Standards for Hazardous Air Pollutants.

Title V Permits will apply to major sources covered under Title I, as well as sources covered under other Title of the Act.

Title VI of the CAA deals with ozone-depleting chemicals. Several solvents used in the pharmaceutical industry are affected by this law. Regulations under Title VI which affect the pharmaceutical industry are discussed in a section of the appendix.

Finally, the specific regulatory requirements developed pursuant to the CAA are described in the last section of this appendix.

National Primary and Secondary Ambient Air Quality Standards

Title I of the CAA establishes the statutory authority for EPA's National Ambient Air Quality Standards (NAAQS) that are to be applied uniformly throughout regions in the United States. The Air Quality Act of 1967 required the designation of air quality control regions (AQCRs) based on "jurisdictional boundaries, urban-industrial concentrations, and other factors including atmospheric areas necessary to provide adequate implementation of air quality standards" [Section 107(a) (1967)]. Today, the United States is divided into 247 AQCRs. Many AQCRs are subdivided into smaller areas based on municipal boundaries, latitudes and longitudes, and other boundaries. A complete list of AQCRs (and their attainment status) is codified at 40 CFR Part 81. An air quality control region is classified as a "nonattainment" area if an NAAQS is violated anywhere in the region. (In the case of ozone, a violation occurs if the 4th highest reading over any 24-hour period in the past 3 years exceeds the NAAQS for ozone.) Two types of NAAQS are set:

- (1) Primary standards that define the level of air quality necessary to prevent any adverse impact on human health**
- (2) Secondary standards that define the level of air quality necessary to protect the public welfare from any known or anticipated adverse effects of a pollutant.**

These standards, promulgated in 40 CFR Part 50, recognize that the severity of the adverse health effects associated with exposure often depends on the duration of exposure. Accordingly, "short-term" standards set limits for a 1-hour, an 8-hour, or a 24-hour period, while "long-term" standards are established on an annual basis.

The EPA has set NAAQS for ozone, carbon monoxide, particulate matter of 10 microns or less (PM-10), sulfur dioxide (SO_x), nitrogen dioxide (NO_x), and lead. These standards are used as a foundation for the regulatory framework discussed in this section. Of the six pollutants, the NAAQS for ozone, NO_x, CO, SO_x and particulate matter are likely to have a significant impact on the pharmaceuticals industry.

Existing Sources of Emissions

Ozone Non-attainment Areas - The "design value" shown in the third column of Exhibit CAA-2 is compared to the 4th highest reading taken over any 24-hour period during 3 concurrent years in a nonattainment area. Based on this value, a nonattainment area is classified as Marginal, Moderate, Serious, Severe, or Extreme. As shown in Exhibit CAA-2, attainment deadlines are based on a sliding scale that reflects the severity of the pollution, where the trigger date is the date when an area is designated as nonattainment.

Exhibit CAA-2 Classification of Ozone Nonattainment Areas

Classification	Deadlines to Attain (from November 15, 1990)	Design Value (ppm)
Marginal	3 Years	0.121 - 0.138
Moderate	6 Years	0.138 - 0.160
Serious	9 Years	0.160 - 0.180
Severe	15 Years 17 Years	0.180 - 0.190 0.190 - 0.280
Extreme	20 Years	Above 0.280

A major source is defined both by the size of the source's facility-wide emissions and the category of the nonattainment area. These conditions are presented in Exhibit CAA-3. In addition, if a firm has the potential to emit more than 100 tons per year (TPY), it is also considered to be a major source. The statement "potential to emit" means the maximum capacity of a stationary source to emit a pollutant under its physical and operational design. Thus operating below capacity does not exclude a plant from being defined as a major source. Any physical or operational limitations on the capacity of the source to emit a pollutant, provided the limitation or its effect on emissions is federally-enforceable, are treated as part of its design and therefore, could mean exclusion from the major category.

Each State is required to develop a State Implementation Plan (SIP) for all nonattainment areas. SIPs contain a range of requirements that are designed to decrease ambient ozone concentrations. Part D of Title I of the CAA provides the authority for implementation of Reasonably Available Control Technology (RACT). A source defined as "major" in a nonattainment area must install the RACT as prescribed in the applicable SIP.

Exhibit CAA-3 Major Source Classifications

Category of Nonattainment Area	Size of VOC or NO _x Sources Affected (Tons/Year)
Extreme	10
Severe	25
Serious	50
Moderate and Marginal	100

EPA has defined RACT as the lowest emission limitation that a particular source is capable of meeting by the application of control technology that is reasonably available considering technological and economic feasibility. RACT for a particular source is determined on a case-by-case basis, considering the technological and economic circumstances of the individual source. Further guidance for RACT is provided in the General Preamble published on April 16, 1992, in 57 *FR* 13498-13570.

EPA regulations provide that less stringent emission limitations than those achievable with RACT are acceptable only if the State plan shows that the less stringent limitations are sufficient to attain and maintain NAAQS, and show reasonable further progress during the interim before attainment.

A single ozone transport region exists for eleven states and the District of Columbia (the northeast ozone transport region). States included in the ozone transport region must submit SIPs to the EPA with special requirements pertaining to enhanced vehicle inspection and maintenance programs and implementation of RACT with respect to all sources of volatile organic compounds in the States. In addition, a stationary source in the ozone transport region that emits or has the potential to emit at least 50 TPY of VOCs for NO_x is considered a major source and is subject to the requirements which would be applicable to major stationary sources if the area were classified as a Moderate nonattainment area.

A determination of the applicable RACT requirements for major sources is usually made by a State on the basis of a case-by-case review of each facility. In an attempt to issue uniform source guidelines, EPA issues Control Techniques Guidelines (CTGs) for industrial categories. The specific CTGs for a source are available through EPA's Technology Transfer Network. There are several CTGs relevant to pharmaceutical plants regarding the control of Volatile Organic Compounds (VOCs) from organic chemical and polymer manufacturing, petroleum and volatile organic liquid storage, and wastewater operations.

New Source Review

Persons constructing new major stationary sources of air pollution or making modifications to major stationary sources are required by the Clean Air Act to obtain a permit before

commencing construction. The process is called new source review (NSR) and is required whether the major source or modification is planned for an area where the NAAQS are exceeded (nonattainment areas) or an area where air quality is acceptable (attainment and unclassifiable areas). Permits for sources in attainment areas are referred to as prevention of significant air quality deterioration (PSD) requirements and include the following:

- ▶ **Installation of Best Available Control Technology (BACT)**
- ▶ **A detailed air quality analysis showing that there will be no violation of PSD "increments"**
- ▶ **Prediction of future air quality standards**
- ▶ **Possible monitoring of air quality for 1 year prior to the issuance of the permit**

EPA determines BACT requirements by: (1) identifying all control technologies; (2) eliminating technically infeasible options; (3) ranking remaining control options by control effectiveness; (4) evaluating the most effective controls and documenting results; and (5) selecting BACT. See *Draft New Source Review Workshop Manual*, U.S. EPA, Office of Air Quality Planning and Standards, October 1990.

- ▶ **Demonstration of standard attainment through the undertaking of an air quality analysis.**

Restrictions in nonattainment areas are more severe. The principal requirements of NSR in nonattainment areas are:

- ▶ **Installation of Lowest Achievable Emission Rate (LAER) technology; LAER is derived from either of the following: (1) the most stringent emission limitation contained in the implementation plan of any State for such class or category of source; or (2) the most stringent emission limitation achieved in practice by such class or category of source. See CAA Part 171 (3).**
- ▶ **Provision for "offsets" representing emission reductions that must be made from other sources. Emissions offsets are generally obtained from existing sources located in the vicinity of a proposed source and must (1) offset the emissions increase from the new source or modification and (2) provide a net air quality benefit. The emission offset ratio depends on the category of the nonattainment area and is listed in Exhibit CAA-4. In general, emission reductions which have resulted from some other regulatory action are not available as offsets. Nonattainment area major source permitting provisions are described in 40 CFR Part 52.24. The PSD permitting provisions are described in 40 CFR Part 52.21.**

Exhibit CAA-4 Major Source Definitions and Offset Ratios in Ozone Nonattainment Areas

Category	Size of Major Source (Tons/Year of VOCs for NO _x)	Offset Ratios
Marginal	100	1.1:1
Moderate	100	1.15:1
Serious	50	1.2:1
Severe	25	1.3:1
Extreme	10	1.5:1

New Source Performance Standards (NSPS)

Major pharmaceutical industry sources must also comply with certain standards of performance developed by EPA (promulgated as 40 CFR Part 60), irrespective of its location in an attainment or nonattainment area. These are technology-based standards and are commonly referred to as the New Source Performance Standards (NSPS). NSPS affect new sources that are to be constructed or existing sources that undergo modifications after the applicable deadlines. NSPS requirements for pharmaceutical industry sources include monitoring, record keeping, and reporting. Further details on affected processes at major pharmaceutical industry sources, dates of applicability and regulatory requirements are provided later in this section.

National Emissions Standards for Hazardous Air Pollutants (NESHAP) and Maximum Achievable Control Technology (MACT) Standards

The NAAQS apply to five primary pollutants and one secondary pollutant: ozone. Ozone precursors typically regulated include VOC emissions from pharmaceutical industry sources as part of the Part 60 requirements, discussed earlier in this section. However, additional risk-based technology standards were developed by EPA for a few selected hazardous air pollutants prior to enactment of the 1990 Amendments to the CAA. These are commonly referred to as NESHAP and were promulgated at 40 CFR Part 61. Like NSPS, NESHAP requirements for pharmaceutical industry sources include monitoring, record keeping, and reporting. Further details on affected processes at major pharmaceutical industry sources, dates of applicability and regulatory summaries are provided later in this section.

Section 112 of the 1990 CAA identified 189 hazardous air pollutants (HAP) for which standards of performance were to be developed based on maximum achievable control technology rather than risk. Existing NESHAPs for those HAPs on the list of 189 would however still apply. Accordingly, EPA promulgated the so-called hazardous organic NESHAP (HON) rule as under 40 CFR Part 63 that sets the MACT standards applicable to specific

industrial sectors. MACT standards for the pharmaceuticals production industry are currently being developed and are scheduled to be promulgated in 1998. Only major sources under Section 112(d) of the Clean Air Act will be regulated. The standards codified under Subparts F, G, H, and I of 40 CFR Part 63 regulate emissions of 112 of the 189 HAPs listed in the CAA.

Section 129 was added to the CAA in 1990 and directs EPA to establish MACT-based regulations for solid waste incinerators. Regulations are currently under development for industrial and commercial waste incinerators.

Permitting Program

The CAA Title V (promulgated as 40 CFR Part 70) defines the minimum standards and procedures required for State operating permit programs. The permit system is a new approach established under the Amendments that is designed to consolidate all of a source's requirements in one document (permit). In addition, State permit fees will generate revenue to fund implementation of the program.

Any facility defined as a "major source" is required to obtain a permit. Part 70.2 defines a source as a single point from which emissions are released or as an entire industrial facility that is under the control of the same person(s), and a major source is defined as any source that emits or has the potential to emit:

- ▶ **10 TPY or more of any hazardous air pollutant**
- ▶ **25 TPY or more of any combination of hazardous air pollutants**
- ▶ **100 TPY of any air pollutant.**

For ozone nonattainment areas, major sources are defined as sources with the potential to emit:

- ▶ **100 TPY or more of volatile organic compounds (VOCs) or nitrogen oxides (NO_x) in areas defined as marginal or moderate**
- ▶ **50 TPY or more of VOCs or NO_x in areas classified as serious**
- ▶ **25 TPY or more of VOCs or NO_x in areas classified as severe**
- ▶ **10 TPY or more of VOCs or NO_x in areas classified as extreme.**

Other sources requiring permits regardless of source size include:

- ▶ **NSPS**
- ▶ **NESHAP**

- ▶ PSD/NSR
- ▶ Acid Rain.

The permit requirement for non-major sources (i.e., area sources) has been deferred for five years.

By November 15, 1993, each State must submit a design for an operating permit program to the EPA for approval. The EPA must either approve or disapprove the State's program within 1 year after submission. Once approved, the State program goes into effect.

Major sources, as well as the other sources identified above, must then develop and submit their permit applications to the State within 1 year (this will take place near the end of 1995). Once a source submits an application, it may continue to operate until the permit is issued. This may take years because permit processing allows time for terms and conditions to be presented to and reviewed by the public and neighboring States, as well as by the EPA. When issued, the permit will include all air requirements applicable to the facility. Among these are compliance schedules, emissions monitoring, emergency provisions, self-reporting responsibilities, and emissions limitations. Five years is the maximum permit term.

As established in Title V (40 CFR Part 70), the States are required to develop fee schedules to ensure the collection and retention of revenues sufficient to cover permit program costs. CAA sets a presumptive fee of \$25 per ton for all regulated pollutants (except carbon monoxide), but States can set higher or lower fees so long as they collect sufficient revenues to cover program costs.

Stratospheric Ozone Protection (40 CFR Part 82)

The CAA Amendments provide for a phase-out of the production and consumption of chlorofluorocarbons (CFCs) and other chemicals that are causing the destruction of the stratospheric ozone layer. Requirements apply to any individual, corporate, or government entity that produces, transforms, imports, or exports these controlled substances.

Section 602 of the Clean Air Act identifies ozone-depleting substances and divides them into two classes. Class I substances are divided into five groups. Section 604 of the Clean Air Act calls for a complete phase-out of Class I substances by January 1, 2000 (January 1, 2002 for methyl chloroform). Class II chemicals, which are hydrochlorofluorocarbons (HCFCs), are generally seen as interim substitutes for Class I CFCs.

Class II substances consist of 33 HCFCs. The law calls for a complete phase-out of Class II substances by January 1, 2030. The schedule for the HCFC phase-out has not yet been finalized; however, EPA has proposed to begin phase-out of some HCFCs by 2002, with a complete phase-out of all HCFCs to take place by 2030. This same proposal would phase-out CFCs, carbon tetrachloride, hydrobromofluorocarbons, and methyl chloroform by

January 1, 1996. Federal regulations do provide essential-use allowances for specific Class I controlled substances for use in metered dose inhalers, as manufactured by the pharmaceutical industry.

On February 11, 1993, EPA issued a rule under Section 611 of the CAA that, effective May 15, 1993, requires both domestically produced and imported goods containing or manufactured with Class I chemicals to carry a warning label. The rule covers items whose manufacture involves the use of Class I chemicals, even if the final product does not contain such chemicals.

Exports are exempt from this rule's labeling requirements, as are products that do not have direct contact with these chemicals. In addition, if direct contact occurs but is non-routine and intermittent (e.g., spot-cleaning of textiles), no labeling is required. Moreover, if a second manufacturer incorporates a product made with an ozone-depleting chemical into another item, the final product need not carry a label.

Section 608 of the CAA established the National Recycling and Emissions Reduction Program. Effective July 1, 1992, EPA prohibited the venting of ozone-depleting compounds used as refrigerants into the atmosphere during maintenance, service, repair, or disposal of air-conditioning or refrigeration equipment. EPA also promulgated regulations at 40 CFR Part 82, Subpart F. Under 40 CFR Part 82, Subpart F on May 14, 1993 which establish standards for service and disposal practices and to require leak repair. Under these regulations, technicians servicing air-conditioning and refrigeration equipment must evacuate refrigerant according to the prescribed guidelines. In addition, recovery and/or recycling equipment used must be certified and all persons who maintain, service, repair, or dispose of appliances must be certified.

Owners of industrial process refrigeration equipment (those with charges greater than 50 pounds) are required to repair substantial leaks. A 35 percent annual leak rate is established for the industrial process and commercial refrigeration sectors as the trigger for requiring leak repairs. Leak repair is required within 30 days of discovery or a 1-year retrofit or retirement plan must be developed for the leaking equipment.

CAA Assessment Considerations

Under Title V of the 1990 Amendments, many CAA requirements have been summarized into one comprehensive permit (risk management is an exception). In general, Title V requirements (40 CFR Part 70 or 71) are the same as compliance provisions previously required under the CAA. The facility's compliance assessor(s) should consider reviewing data derived from previous facility self-assessments or when determine compliance with Title V requirements. The regulatory inspection forms are generally organized around process equipment (called emission units) and stacks or vents (called emission points). The facility assessor should develop an assessment format where any enforceable limits and

the underlying regulatory requirements applying to the emission unit or the emission point is listed so that it can be confirmed during the assessment.

In general, not all of the applicable requirements can be verified during a single self-assessment and each assessment represents a "snapshot" of compliance. In recognition of the fact that a facility assessor can not always be in place to detect violations, "baseline" assessment techniques stress the importance of maintenance plans to ensure proper operation and maintenance of equipment. Baseline assessment techniques also emphasize tracking of operating parameters (such as incinerator temperatures) during assessments for future use in accessing equipment performance. This focus on self-monitoring and self-reporting was reinforced under Title V with requirements for enhanced monitoring, periodic monitoring, compliance plans and programs and maintenance plans. The facility self-assessor can rely upon baseline techniques to ensure that the systems and programs established for self-monitoring and self-reporting are appropriately designed and successfully implemented.

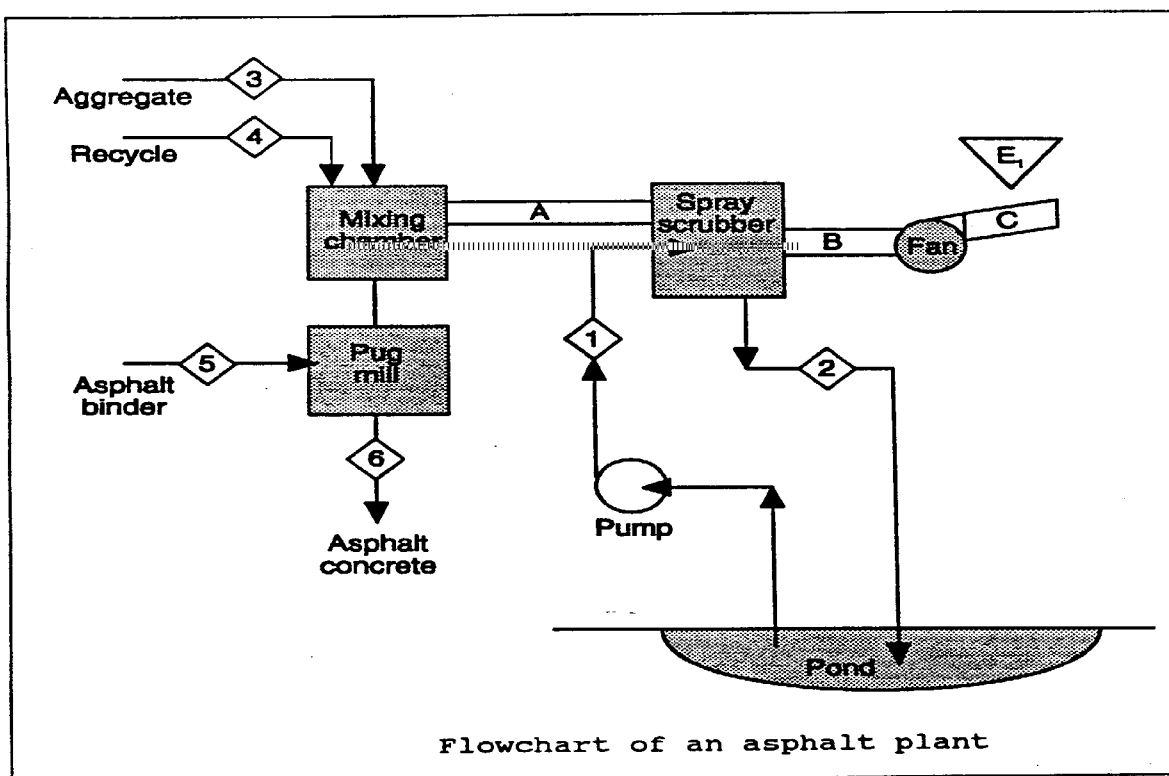
The draft Compliance Assurance Monitoring (CAM) Rule will supplant enhanced and periodic monitoring requirements and focuses on the same type of monitoring of equipment performance or other parameters that indicate compliance with applicable requirements. As an example, a emission unit that controls emissions of volatile organic compounds (VOCs) through exhaust gas incineration might have a lower allowable operating temperature of 1800 °F. Using baseline assessment techniques, the assessor routinely records this operating temperature. If this unit had traditionally operated at 2000 °F, and now operated at 1825 °F, this would not constitute a violation of the 1800 °F limit, but might indicate a potential for violation and a need for follow-up actions. Under the CAM Rule, the facility might choose to record and report this temperature to demonstrate continued compliance with applicable requirements. However, the facility assessor should also initiate appropriate follow-up actions to investigate the existence of a problem that might result in a violation of the requirement, and pursue proactive compliance assurance measures.

The applicable CAA regulations for a pharmaceutical manufacturing facility will vary with location. Those facilities located near urban areas are much more likely to be subject to nonattainment provisions. Ozone nonattainment areas have RACT requirements on all major sources of VOCs and NO_x. RACT requirements vary with location and severity on nonattainment; however, pharmaceutical manufacturing facilities would generally have RACT requirements on reactors, distillation units, storage tanks, pumps and valves. NSPS requirements are based on the capacity and on the age of regulated units, but apply nationally to conforming units. NSR requirements generally contain the most stringent emissions or performance limits and apply to new units as they are constructed. BACT applies under the PSD program in areas that meet NAAQS; LAER applies under NSR permits issued in nonattainment areas. MACT standards apply nationally based on magnitude of emissions of 189 HAPs. Units that are subject to these requirements would receive priority in an air quality inspection.

The process oriented self-assessment approach focuses on following a process from start to finish and developing process flow diagrams to identify key points for inspection. Previous facility assessment techniques generally focused more on individual emission units and emission points without as much attention to understanding the process. An example of an assessment process diagram is included as Exhibit CAA-5. This type of approach is also more compatible with a multimedia self-assessment technique in that the process diagrams could contain information on other items such as wastewater discharge or pollution prevention activities.

Title V (or Part 70) permits will present new challenges to the compliance self-assessment. One of these challenges will be inclusion of plant wide emissions limits or caps. Plant wide caps offer operational flexibility to the permittee because changes in use of different processes can occur and as long as overall emissions remain under the limits, no permit terms are violated. The assessor will need to sum emissions from multiple processes in order to determine compliance. Alternative operating scenarios are another example of Part 70 permit conditions that offer operational flexibility. Alternative operating scenarios describe different methods of operation for process equipment; these scenarios will contain different emissions limits based on different production modes. Confirmation of different limits on one process substantially complicates the self-assessment. One other aspect of the Part 70 permit is the permit shield. If a facility is operating within the limits of the Part 70 permit, then the permit shields the facility against charges of noncompliance for those activities.

Exhibit CAA-5. Example Inspection Process Diagram



As mentioned in the description of baseline inspection techniques, self-monitoring and self-reporting activities are important to maintaining compliance. Part 70 requires compliance programs for units operating out of compliance with applicable regulations. Maintenance and compliance plans are required for all facilities. These programs would be used to document efforts to maintain control equipment and replace parts prior to break-downs that could result in excess emissions. The investigator should attempt to verify through evaluation of records the adequacy of these programs.

CAA Regulatory Requirements

The following sections provide summaries of the principal regulations developed pursuant to the CAA that may apply to the pharmaceutical industry. The section includes:

- ▶ **40 CFR Part 60**
 - Subparts D_a, D_b, D_c Standards of Performance for Steam Generating Units
 - Subpart K_b Standards of Performance for VOC Storage Vessels
 - Subpart GG Standards of Performance for Stationary Gas Turbines
- ▶ **40 CFR Part 61**
 - Subpart J National Emissions Standards for Equipment Leaks (Benzene)
 - Subpart M National Emissions Standards for Asbestos
 - Subpart V National Emissions Standards for Equipment Leaks (Fugitive Emission Sources)
 - Subpart Y National Emissions Standards for Benzene Emissions from Benzene Storage Vessels
- ▶ **40 CFR Part 63**
 - Subpart H National Emissions Standards for Organic Hazardous Air Pollutants from SOCM for Equipment Leaks
 - Subpart I National Emissions Standards for Organic Hazardous Air Pollutants for Certain Processes Subject to the Negotiated Regulation for Equipment Leaks
 - Subpart Q National Emissions Standards for Hazardous Air Pollutants for Industrial Cooling Towers
- ▶ **40 CFR Part 68** Chemical Accident Prevention Provisions
- ▶ **40 CFR Part 82** Protection of Stratospheric Ozone

Applicability:

- Electric utility steam generating units capable of combusting > 73 MW (250 million BTU/hr) heat input alone, or in combination with other fossil fuels.
- Electric utility combined cycle gas turbines with duct burners capable of combusting > 73 MW (250 million BTU/hr) heat input of fossil fuel.

40 CFR Part 60 - Subpart D_a **Standards of Performance for Electric Utility Steam Generating Units for which construction is commenced after September 18, 1978.**

- Standards for:, particulate matter 60.42a, sulfur dioxide 60.43a, nitrogen oxides 60.44a
- Test Methods 60.48a
- Monitoring 60.47a
- Reporting and record keeping 60.49a

Date of Applicability:

- Sources constructed, reconstructed, or modified after September 18, 1978.

Affected Processes:

Emission standards for all affected facilities for:

- Particulate Matter (PM) of 13 ng/J (0.03 lb/mmBtu) heat input from the combustion of solid, liquid or gaseous fuel
- Opacity of 20%, averaged over 6 minutes, except for one 6 min. period per hour of 27% opacity (block average).
- SO₂, when combusting solid or solid-derived fuels: 520 ng/J (1.20 lb/mmBtu) heat input and 90% reduction; or 70% reduction when emissions are < 260 ng/J (0.60 lb/mmBtu heat input). All limits and percent reductions are based on a 30-day rolling average (continuous compliance by CEMS).
- SO₂, when combusting liquid or gaseous fuels: 340 ng/J (0.80 lb/mmBtu) heat input and 90% reduction; or 86 ng/J (0.20 lb/mmBtu heat input). All limits and percent reduction requirements are based on a 30-day rolling avg. (continuous compliance by CEMS).

Alternative limits for SO₂ apply if facility meets one of the following criteria

- **combusts solid solvent refined coal (SRC-1) (60.43a(c))**
 - **combusts 100% anthracite (60.43a(d)(1))**
 - **is classified as a resource recovery facility (60.43a(d)(2))**
 - **is located in a noncontinental area and combusts solid or solid-derived fuel (60.43a(d)(3))**
 - **is located in a noncontinental area and combusts liquid or gaseous fuel (60.43a(e))**
 - **combusts different fuels simultaneously (60.43a(h))**
- **NO_x (NO₂) of various limits in ng/J (lb/mmBtu) heat input depending on fuel type, based a 30-day rolling avg (continuous compliance by CEMS). If two or more fuels are combusted simultaneously, the formula in 60.44a(c) should be used.**

Exemptions:

- **Subpart D_a applies to emissions from fossil fuels only. Gas turbine emissions are subject to Subpart GG.**
- **Changes to existing fossil fuel-fired steam generating units to allow for the use of combustible materials, other than fossil fuels.**
- **Changes to existing fossil fuel-fired steam generating units from its original design of gaseous or liquid fossil fuels to accommodate the use of any other fossil or nonfossil fuel.**

Partial Exemptions:

Emissions reduction requirements for SO₂ do not apply if facility is operated under an SO₂ commercial demonstration permit issued by the Administrator under the provisions of 60.45a.

Emissions levels for NO_x do not apply if unit is combusting coal-derived liquid fuel and is operating under a commercial demonstration permit issued by the Administrator under the provisions of 60.45a.

Monitoring Requirements:

- 1) Maintenance and operation of continuous emission monitoring system (CEMS), for monitoring opacity according to 60.47a(a),(h) and (j) except where only gaseous fuel is combusted.
- 2) Maintenance and operation of continuous emission monitoring system (CEMS), for monitoring SO₂ except where only natural gas is combusted. SO₂ is to be monitored at the sulphur dioxide control device inlet and outlet, unless subject to 68.47a(b)(2) or (3).
- 3) Maintenance and operation of continuous emission monitoring system (CEMS), for monitoring NO_x emissions according to 60.47a(c).
- 4) Maintenance and operation of continuous emission monitoring system (CEMS) for monitoring O₂ or CO₂ content of flue gases at each location where SO₂ or NO_x is monitored.
- 5) CEMS minimum data availability ≥ 18 hours a day for ≥ 22 days a month.

Reporting Requirements:

- 1) Initial performance test data and CEMS performance evaluation data for SO₂, NO_x and opacity.
- 2) Quarterly reports including:
 - the information collected for 30 successive boiler operating days as specified in 60.49a(b) for sulfur dioxide and nitrogen oxides. If the minimum quantity of data is outlined in 60.49a(c) and/or is information is not collected over 30 days or the data is not available, then the information to be reported is outlined in 60.49a(c) and/or 60.49a(f)
 - the information in 60.49a(d) if standards are exceeded during emergency conditions because of control system malfunction
 - the information in 60.49a(e) if SO₂ fuel pretreatment is claimed
 - signed statement in 60.49a(g)
 - excess emission reports as under 60.7

Applicability:

Steam generating units with a heat input capacity from fuels combusted in the steam generating unit > 29 MW (100 million BTU/hr).

40 CFR Part 60 - Subpart D_b **Standards of Performance for Industrial, Commercial, Institutional Steam Generating Units**

- Standards for: sulfur dioxide 60.42b, particulate matter 60.43b, nitrogen oxides 60.44b
- Test Methods 60.45b, 60.46b
- Monitoring 60.47b, 60.48b
- Reporting and record keeping 60.49b

Date of Applicability:

- Sources constructed, reconstructed, or modified after June 19, 1984.
- Sources meeting applicability and constructed, reconstructed, or modified after June 19, 1984 but before June 19, 1986 (PM, NO_x, SO₂)

Affected Processes:

For all affected facilities which combust coal, oil, wood or municipal waste (alone, or in combination with other fuels):

Emission standards for:

- Particulate Matter (PM) of 22 ng/J (0.05 lb/mmBtu) to 86 ng/J (0.20 lb/mmBtu) depending on fuel type and other factors, over 6 hr period
- Opacity of 20%, averaged over 6 minutes, except for one 6 min. period per hour of 27% opacity (block average).
- SO₂ of various limits in ng/J (lb/mmBtu) heat input depending on fuel type and other factors, based on a 30-day rolling average (continuous compliance by CEMS) unless unit has Federally enforceable low capacity factor for oil (10% or less), combusts only very low sulphur oil, and does not combust other fuels.
- NO_x (NO₂) of various limits in ng/J (lb/mmBtu) heat input depending on fuel type based a 30-day rolling avg. (continuous compliance by CEMS), unless unit has a Federally enforceable low capacity factor, or low nitrogen fuels. In this case, compliance determined based on performance tests (specified in 60.44b(j)(1)-(3)).

Exemptions:

- Steam generating units meeting Subpart D_c applicability or Subpart D_a (electric utility steam generating units) applicability are not subject to Subpart D_b.
- Existing steam generating units modified for the sole purpose of combusting gases containing TRS as defined under 60.28.

Partial Exemptions:

Steam generating units at petroleum refineries subject to 40 CFR Part 60, Subpart J or incinerators subject to 40 CFR Part 60, Subpart E are subject to Subpart Db only for PM and NO_x.

Steam generators subject to Subpart J who have a heat input capacity of ≤ 73 MW (260 mmBtu/hr) are not subject to NO_x emissions standards.

Percent reduction requirements not applicable to affected facilities

- for SO₂ if one of the following criteria apply:
 - annual capacity for coal and oil $\leq 30\%$ (subject to Federal enforceable permit limiting operation to annual capacity factor $\leq 30\%$)
 - located in noncontinental areas
 - facility is combusting coal or oil in a gas turbine duct burner and $\geq 70\%$ of the heat input is from exhaust gases entering the duct burner.
 - burning very low sulfur oil

Monitoring Requirements:

- 1) If subject to SO₂ standard in 60.42(b), maintenance and operation of inlet/outlet continuous emission monitoring system (CEMS), for monitoring SO₂ concentrations and either O₂ or CO₂. Or, measurement of SO₂ emissions according to 60.47b(1)-(4). If burning low sulfur oil, may use fuel supplier certification.
- 2) If subject to opacity standard under 60.43(b) maintenance and operation of continuous monitoring system (COMS) to measure opacity of emissions.

- 3) **If subject to the nitrous oxides standards of 60.44b, maintenance and operation of COMS to measure NO_x emissions not required for duct burners used in combined cycle system or low capacity nitrogen fuel facilities that are subject to the performance test emission standards.**
- 4) **CEMS minimum data availability ≥ 75 percent of hours per day and ≥ 75 percent of days per month.**

Record keeping Requirements (2 years):

- 1) **All opacity data**
- 2) **Amount of each fuel combusted daily with recorded calculation of annual capacity factors, maintained on a quarterly basis**
- 3) **Performance test data and initial performance test data**
- 4) **Nitrogen content of residual oil combusted in affected facility.**
- 5) **For facility subject to nitrous oxide standards: daily records of steam generating unit operations (60.49b(g)(1)-(10))**

Reporting Requirements:

- 1) **Compliance reports quarterly for each applicable pollutant (NO_x and SO₂) ; semi-annually if no exceedances.**
- 2) **Quarterly report of information specified in 60.49b(g) for nitrous oxide if subject to CEMS requirement under 60.48b(b).**
- 3) **Plan for NO_x monitoring operating conditions, if applicable.**
- 4) **Quarterly report for sulfur dioxide as described in 60.49b(j)-(m).**

Applicability:

Steam generating unit with maximum design heat input capacity of ≤ 29 MW (100 mmBtu/hr) but ≥ 2.9 MW (10 mmBtu/hr).

Date of Applicability:

- Sources constructed, reconstructed, or modified after June 9, 1989.

40 CFR Part 60 - Subpart D_c **Standards of Performance for Small Industrial-Commercial-Institutional Steam Generating Units**

- Standards for: sulfur dioxide 60.42c and particulate matter 60.43c
- Test Methods 60.44c, 60.45c
- Monitoring 60.46c, 60.47c
- Reporting and Record keeping 60.48c

Affected Processes:

Emission standards for:

- SO₂ of various levels of ng/J (lb/mmBtu), depending on fuel type and other factors. Based on a 30-day rolling average unless facility listed in 60.42c(h)(1), (2), or (3); then compliance with emission limits or fuel oil sulphur limits may be determined based on certification from fuel supplier as in 60.48c(f)(1), (2), or (3).
- Particulate Matter (PM) of 22 ng/J (0.05 lb/mmBtu) to 130 ng/J (0.30 lb/mmBtu) depending on fuel type and other factors
- Opacity of 20% for facilities with heat input capacity ≥ 8.7 MW and combusting coal, wood, or oil, averaged over 6 minutes, except for on 6 minute period per hour of 27% opacity.

Exemptions:

- Percent reduction for SO₂ not applicable to facilities that combust coal (alone or in combination with other fuels) that meet the following criteria:
 - heat input capacity ≤ 22 MW
 - annual capacity factor for coal $\leq 55\%$ and subject to Federally enforceable low capacity factor located in noncontinental areas
 - facility is combusting coal in a duct burner and $\geq 70\%$ of the heat input is from exhaust gases entering the duct burner.

- Percent reduction for SO₂ not applicable to facilities that combust oil as in 60.42c(d).

Monitoring Requirements:

- If subject to SO₂ standard, maintenance and operation of outlet continuous emission monitoring system (CEMS) for monitoring SO₂ and either O₂ or CO₂. Inlet CEMs for SO₂ and either O₂ or CO₂ if % reduction requirements apply. Or, measurement of SO₂ emissions according to 60.46c(d)(1)-(3).
- Facilities subject to 60.42c(h)(1), (2), or (3) that demonstrate compliance with SO₂ standards based on fuel supplier certification, must keep records of certifications in lieu of CEMS.
- For PM: Maintenance of continuous monitoring system (COMS) for opacity if combust coal, wood or residual oil (alone or in combination with other fuels).

Record keeping Requirements (2 years):

- 1) All SO₂ monitor data as described in 60.46c(f)
- 2) Fuel supplier certification records (specified 60.48c(f)(1)-(3)).
- 3) Amounts of each fuel combusted during each day
- 4) If subject to a Federally enforceable low-capacity factor, calculation of annual capacity factor for each fuel combusted.

Reporting Requirements:

- 1) Notification of date of construction, reconstruction, anticipated and actual startup as in 60.48c(a)(1-4).
- 2) Initial and subsequent performance tests
- 3) Excess emission reports (EER) quarterly for opacity; semi-annually if no exceedances.
- 4) Quarterly report for SO₂ emissions/monitoring data (specified in 60.48c(e)(1)-(11)).

Applicability:

- Stationary gas turbines with heat input at peak load ≥ 10.7 gigajoules/hour, based on lower heating value of the fuel fired.

40 CFR Part 60 - Subpart GG **Standards of Performance for Stationary Gas Turbines**

- Standards for: nitrogen oxides 60.332, sulfur dioxide 60.333
- Monitoring 60.334
- Test Methods 60.335
- Reporting and record keeping 60.334

Date of Applicability:

- Sources constructed, reconstructed, or modified after October 3, 1977, except as provided in 60.332(e) and (j).

Affected Processes:

Emission standards for:

- NO_x according to the standard (STD) equation outlined in 60.332(a)(1) or (2), as directed in 60.332(b),(c), and (d)
- SO₂ emissions of $\leq 0.015\%$ by volume at 15% O₂ on a dry basis or fuel which contains $< 0.8\%$ sulfur by weight.

Exemptions:

- Standards for NO_x are not applicable for gas turbines outlined in 60.332(e) - (l).

Monitoring Requirements:

- For units using water injection to control NO_x, continuous monitoring system to monitor and record the fuel consumption and ratio of water to fuel being fired in the turbine, within 5% accuracy
- Monitoring of fuel sulfur and nitrogen content as specified in 60.334(b)(1)-(2).

Reporting Requirements:

Quarterly reports as required under 60.7, including reports of excess emissions data. The periods of excess emissions to be reported are outlined in 60.334 (c)(1)-(4). The calculation of emissions rates are outlined in 60.335.

Applicability:

- Storage vessels with design capacity $\geq 151\text{m}^3$, containing a VOL with TVP ≥ 5.2 kPa but less than 76.6 kPa

40 CFR Part 60 - Subpart K_b Standards of Performance for VOC Storage Vessels

- Monitoring 60.116b
- Record keeping and Reporting 60.115b
- Test methods 60.113b

- Storage vessels with design capacity $\geq 75\text{m}^3$, but $\leq 151\text{m}^3$, containing VOL with TVP ≥ 27.6 kPa but less than 76.6 kPa
- Storage vessels with design capacity $\geq 75\text{m}^3$ and TVP > 76.6 kPa

40 CFR PART 60 - SUBPART K _b	
AFFECTED PROCESSES	REGULATORY THRESHOLD
Storage vessel must be equipped with either: Fixed roof with internal floating roof meeting the specifications in 60.112b(a)(1) External floating roof meeting the specifications in 60.112b(a)(2) Closed vent systems and control device meeting the specifications in 60.112b(a)(3) Vessels with design capacity $\geq 75\text{m}^3$ and TVP $> 76.6\text{kPa}$ must be equipped with a closed vent system and control device, or equivalent	If detectable emissions > 500 ppm above background Reduce VOC emissions by 95% or greater. Flares must meet requirements of 60.18

Date of Applicability:

Sources constructed, reconstructed or modified after July 23, 1984.

Exemptions:

- Coke oven by-product plants
- Pressure vessels designed to operate in excess of 204.9 kPa
- Vessels permanently attached to mobile vehicle
- Vessels with design capacity $\leq 1,589.874\text{ m}^3$ used for petroleum or condensate stored, processed, or treated prior to transfer
- Vessels at bulk gasoline plants
- Storage vessels at gasoline service stations
- Vessels to storage beverage alcohol

Monitoring Requirements:

- 1) Visual inspections of vessels and fixed roof and internal floating roof as described in 60.113b(a) and of vessels with external floating roofs as described in 60.113b(a) and of vessels with external floating roofs as described in 60.113b(b)(6)
- 2) Determine gap areas and maximum gap widths of vessels with external floating roofs as described in 60.113b(b).
- 3) Monitor parameters of closed vent system and control device in accordance to operating plan
- 4) Monitor flares as required in 60.18

Record Keeping Requirements (at least 2 years):

- 1) Visual inspection data
- 2) Storage vessel dimensions and capacity
- 3) VOL storage information as applicable under 60.116b(c)
- 4) Gap measurements if floating roof
- 5) Storage vessels with design capacity $\geq 40\text{m}^3$, must keep records of vessel dimension and capacity

Reporting Requirements:

- 1) Notification to the Administrator 30 days prior to filling storage vessel required to be inspected under 60.113b(a)(1), 60.113b(a)(4), or 60.113b(b)(6) or required to determine gap measurements required under 60.113b(b)(1)
- 2) Operating plan for closed vent system and control device as in 60.113b(c)(1)
- 3) Initial report describing control equipment and certification, and required measurements
- 4) Report any defects within 30 days

Applicability:

- Sources intended to operate in benzene service including pumps, compressors, pressure relief devices, sampling connections, systems, open-ended valves or lines, valve flanges and other connectors, product accumulator vessels, and control devices .
- Required to comply with Part 61, Subpart V

40 CFR Part 61 - Subpart J
**National Emission Standard for Equipment
Leaks (Fugitive Emission Sources of Benzene)**

Date of Applicability:

All existing sources

Exemptions:

- Sources located in coke by-product plants
- Plant sites designed to produce or use less than 1,000 mg/year
- Any process unit that has no equipment in benzene service

Monitoring Requirements:

Requirements in Part 61, Subpart V

Applicability:

- 61.145 is applicable to owners or operators of a demolition or renovation activity
- 61.146 is applicable to owners or operators of an operation in which asbestos-containing materials are spray applied.

40 CFR Part 61 - Subpart M National Emission Standard for Asbestos

- Standard for Demolition and Renovation 61.145
- Standard for Spraying 61.146
- Standard for Insulating Materials 61.148
- Standard for Waste Disposal for Manufacturing, Fabricating, Demolition, Renovation, and Spraying Operations

Affected Processes:

- For demolition, requirements in 61.145(b) and (c) apply if the combined amount of Regulated Asbestos-Containing Material (RACM) meets criteria listed in 61.145(a)(1)(i) or (ii)
- For renovation, requirements in 61.145(b) and (c) apply if the combined amount of RACM to be stripped, removed, dislodged, cut, drilled, or disturbed meets the criteria in 61.145(4)(i) or (ii)
- All RACM must be removed from a facility being demolished or renovated before any activity begins that would break up, dislodge, or disturb the material or preclude access to the material for removal
- When a facility component that contains, is covered with, or is coated with RACM is being taken out of the facility as a unit or in sections, the procedures in 61.145(c)(2) must be followed; and when RACM is stripped from a facility component while it remains in place at the facility, procedures in 61.145(c)(3) must be met
- After a facility component covered with, coated with, or containing RACM is taken out of the facility, it must be handled according to the procedures in 61.145(c)(4). Large components such as reactor vessels, large tanks, and steam generators must be handled according to procedures in 61.145(c)(5)
- All RACM must be handled according to procedures in 61.145(c)(6)
- No RACM can be stripped, removed, or otherwise handled or disturbed at a facility unless at least one onsite representative is trained in compliance with the regulations
- Under 61.146, material that contains more than 1% asbestos cannot be used for spray application on buildings, structures, pipes, and conduits

- Under 61.148, no owner or operator may install or reinstall on a facility component any insulating materials that contain commercial asbestos if the materials are either molded and friable or wet-applied and friable after drying and this does not apply to spray-applied insulating materials regulated under 61.146
- Under 61.150, each owner or operator of any source covered under 61.145 or 61.146 must:
 - Discharge no visible emissions to the outside air during the collection, processing, packaging, or transporting any asbestos-containing waste material generated by the source, or use one of the emission control and waste treatment methods specified in 61.150(a)((1) through (4)
 - Dispose of all asbestos-containing waste material as soon as practical at sites as listed in 61.150(b)
 - Mark vehicles used to transport asbestos-containing waste material as in 61.150(c)

Exemptions:

- If the facility is being demolished under State or local government order because the facility is structurally unsound or in danger of imminent collapse, only 61.145(b)(1), (b)(2), b(3)(iii), (b)(4) (except (b)(4)(VIII)), (b)(5), and (c)(4) through (c)(9)
- RACM does not need to be removed before demolition if it meets the criteria in 61.145(c)(1)(I), (ii), (iii), or (iv)
- Spray-on application of materials is not subject to 61.146 when the asbestos fibers in the materials are encapsulated with a bituminous or resinous binder during spraying and the materials are not friable after drying
- Owners and operators of sources subject to 61.146 are exempt from the requirements of 61.05(a), 61.07, and 61.09.
- Requirements in 61.150(a) do not apply to demolition and renovation for Category I nonfriable ACM waste and Category II nonfriable ACM waste that did not become crumbled, pulverized, or reduced to powder

Reporting and Record Keeping Requirements

- Owner or operator of demolition or renovation activity must submit and update written notice containing the information in 61.145(b)(4)(I) through (xvii)

- **Spray-on application of materials that contain more than 1% asbestos on equipment and machinery are subject to the notification and procedural requirements in 61.146(b)(1) and (2)**
- **Waste shipment records must be maintained for all asbestos-containing waste as described in 61.150(d)**

Applicability:

- Sources intended to operate in VHAP service including pumps, compressors, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, flanges and other connectors, product accumulator vessels, and control devices.

40 CFR Part 61 - Subpart V **National Emission Standard for Equipment Leaks (Fugitive Emission Sources)**

- Monitoring 61.242, 61.245
- Reporting 61.247
- Record Keeping 61.246

40 CFR PART 61 - SUBPART V	
AFFECTED PROCESSES	REGULATORY THRESHOLD
Pumps	If measured leak 10,000 ppm or more, or if indication of liquids dripping from pump seal
Compressors	Facility required to determine a criterion that indicates failure of the seal system and/or barrier fluid system.
Valves	If measured leak 10,000 ppm or more. Alternative standards 1 and 2, leak is detected if more than 2% if valves emitting 10,000 ppm or more.
Pressure relief devices in gas/vapor service	If detectable emissions greater than 500 ppm above background.
Pressure relief devices in liquid service and flanges and other connectors	If measured leak 10,000 ppm or more.
Closed-Vent Systems	Leak is detected if detectable emissions greater than 500 ppm.
Control devices	Vapor recovery systems must recover vapors with 95% efficiency or greater. Combustion devices must recover vapors with 95% efficiency or greater and must provide a minimum residence time of 0.5 seconds at minimum temperature of 760 °C.

Date of Applicability:

After date of promulgation of specific Subpart in Part 61.

Exemptions:

None

Monitoring Requirements:

- 1) **Pumps—Weekly visual inspection (not required if pump within boundary of unmanned plant site) and monthly instrumental monitoring using RM 21. Instrumental monitoring of pumps equipped with a dual mechanical seal system is required only if indication of liquid drippings from pump seal. Instrumental monitoring of pumps designated for no detectable emission is required annually.**
- 2) **Compressors—Daily check of sensor or equip sensor with audible alarm. If compressor is equipped with closed vent system capable of capturing and transporting leak to control device, annual monitoring using RM 21.**
- 3) **Valves—Monthly instrumental monitoring using RM 21 (unless leak not detected for 2 successive months, then quarterly monitoring) or implementation of Alternative 1 or 2.**
- 4) **Pressure relief devices in gas/vapor service—Monitoring using RM 21 within 5 days of pressure release.**
- 5) **Pressure relief devices in liquid service and flanges and other connectors—Monitoring using RM 21 within 5 days of detecting potential leak.**
- 6) **Closed vent systems—Initial and annual monitoring.**

Reporting requirements:

- 1) **Initial notification that requirement is being implemented as required under 61.247(a).**
- 2) **Semiannual report (including information on leaks and repairs) as required under 61.247(b).**

Record keeping requirements:

- 1) **Tagging leaking equipment with ID# until after 2 successive months with no detected leaks.**
- 2) **Information on leaking equipment and repairs as required under 61.246(c), kept for 2 years.**
- 3) **Equipment design information for closed-vent systems and control devices as described in 61.246(d).**
- 4) **Information on equipment to which a standard applies as described in 61.246(e).**

- 5) **Information on valves as required under 61.246(f) and (g).**
- 6) **Design criterion as described in 61.246(h).**
- 7) **Information related to exemptions as described in 61.246(l) and (j).**

Applicability:

- All benzene storage vessels with a design capacity $\geq 38 \text{ m}^3$ (10,000 gal)

Affected Processes:

- Storage vessels storing benzene having specific gravities as indicated in 61.270(a)
- Storage vessel must be equipped with either:
 - 1) Fixed roof and internal floating roof, meeting the specifications in 61.271(a).
 - 2) External floating roof meeting the specifications in 61.271(b).
 - 3) Closed vent system and control device meeting the specifications in 61.271(c). Operated with emissions $< 500 \text{ ppm}$ above background and a control device to reduce benzene emissions by 95% or greater.

40 CFR Part 61 - Subpart Y **National Emission Standard for Benzene Emissions from Benzene Storage Vessels**

- Monitoring 61.272
- Record keeping 61.276
- Reporting 61.274 & 61.275

Date of Applicability:

All existing sources.

Exemptions:

- Vessels at coke-byproduct facilities
- Vessels permanently attached to trucks, rail cars, barges or ships
- Pressure vessels designed to operate in excess of 204.9 kPa and without emissions to the atmosphere
- If also subject to 40 CFR Part 60, Subparts K, K_a, K_b, must comply only with the Subpart with the most stringent standards.

Monitoring Requirements:

- 1) Visual inspections of vessels with fixed roof and internal floating roof as described in 61.272(a).

- 2) Determine gap areas and widths between primary and secondary seals and the vessel wall as in 61.272(b), and conduct visual inspections of each time a vessel with external floating roof is emptied and degassed as in 61.272(b)(6).
- 3) Monitor parameters of closed vent systems and control devices in accordance with operating plan.
- 4) Monitor flares as required in 60.18.

Record keeping requirements:

- 1) Maintain records showing dimensions of storage vessel and analysis of capacity as long as vessel is in operation. This requirement is also applicable to storage vessels with a design capacity $< 38 \text{ m}^3$.
- 2) Records related to vessels equipped with closed vent systems with control devices as described in 61.276(c) (maintain for at least 2 years).

Reporting requirements:

- 1) Vessels with fixed roofs and internal floating roofs, and vessels with external roofs: Notification to the Administrator 30 days prior to filling storage vessel required to be inspected under 61.272(a)(1), (a)(3), or b(6).
- 2) Operating plan for closed vent system and control device that meets the requirements of 61.272(c)(1).
- 3) Initial report describing control equipment and other information as required under 61.274(a) and (b) (all affected storage vessels).
- 4) Periodic reports describing inspection results of vessels with fixed roof and internal floating roofs [61.275(a), (b) and (c)], and describing results of seal gap measurements of vessels with external floating roofs [61.275(d)].
- 5) Quarterly reports of each occurrence that results in excess emissions for vessels equipped with closed vent systems with control devices [61.275(e)].

Applicability:

- Applies to pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, connectors, surge control vessels, bottoms receivers, instrumentation systems, and control devices or systems used to operate an organic HAP for 300 hours or more during a calendar year

40 CFR Part 63- Subpart H

National Emissions Standards for Organic Hazardous Air Pollutants from the Synthetic Organic Chemical Manufacturing Industry for Equipment Leaks

- Monitoring 63.180
- Record keeping 63.181
- Reporting 63.182

40 CFR PART 63 - SUBPART H	
AFFECTED PROCESSES	REGULATORY THRESHOLD
Pumps in light liquid service	Must determine Phase (I, II, or III) as per provisions in 63.163 and the applicable threshold for leak detection
Compressors	Must be equipped with a seal system that prevents leakage to atmosphere and complies with provisions in 63.164
Pressure relief devices in gas/vapor service	Must have detectable emissions < 500 ppm above background and must comply with other provisions in 63.165
Sampling connection systems	Must be equipped with a closed-vent system that returns the purge to the process and complies with provisions in 63.166
Valves in gas/vapor service and in light liquid service	Must determine Phase (I, II, or III) as per provisions in 63.168 and the applicable threshold for leak detection
Pumps, valves, connectors, and agitators in heavy liquid service; instrumentation systems; and pressure relief devices in liquid service	Must report leaks detected by visual, olfactory, audible or any other method must be repaired by methods specified in 63.180
Surge control vessels and bottoms receivers	If not routed back to the process and meets conditions specified in Table 2 or 3 must be equipped with closed-vent system
Closed-vent system and control devices	Must comply with requirements as per 63.172
Agitators in gas/vapor and light liquid service	Must be monitored monthly to detect leaks as per 63.173 and comply with all provisions therein
Connectors in gas/vapor and light liquid service	Must be monitored to detect leaks as per 63.174 and comply with all provisions therein

Date of Applicability:

Dates are specified in Subpart F (63.100(k))

Exemptions:

- Lines and equipment not containing process fluids

Monitoring Requirements:

Compliance with Method 21 of 40 CFR 60, App. A, and other provisions in 63.180(b)

Record Keeping Requirements:

Only one record keeping system must be maintained for all process units at one plant. Information must be maintained as described in 63.181(b)-(k) including: identification numbers for all affected process units; initial and periodic reports, delay of repair records; design specifications and performance demonstration activities; documentation for all quality assurance programs implemented; notifications of compliance status

Reporting Requirements:

- 1) Initial notification as described in 63.182(b)
- 2) Notification of compliance status as described in 63.182(c)
- 3) Semiannual reports as described in 63.182(d)

Applicability:

Major sources (including pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, connectors, surge control vessels, bottoms receivers, and instrumentation

systems that are intended to operate in organic hazardous air pollutant services for 300 hours or more during the calendar year)

40 CFR Part 63 - Subpart I **National Emission Standards for Organic Hazardous Air Pollutants Certain Processes Subject to the Negotiated Regulation for Equipment Leaks**

Affected Processes:

Emissions of designated organic HAPs from the following processes: styrene-butadiene rubber production, polybutadiene rubber production, agricultural chemicals as identified in §63.190(b)(3), polymers/resins or other chemical products listed in §63.190(b)(4), pharmaceutical production processes using carbon tetrachloride or methylene chloride, and processes producing the polymers/resins or other chemical products listed in §63.190(b)(6).

Date of Application:

Variable dates, but not later than April 22, 1997

Exemptions:

Temporary exemption, provided that notification and certification is provided, for facilities that emit less than 10 tons per year of any individual HAP, and less than 25 tons per year of any combination of HAPs.

Requirements:

Owners and operators of subject sources must comply with the requirements of Subpart H for the processes and designated organic HAPs and certain provisions of Subpart A, as identified in §63.192(b). Also, all facilities subject to this subpart must receive a permit under 40 CFR Part 70 or 71.

Record Keeping:

All records required in Subpart H and in §63.192(f)(2) for at least two years, except as otherwise specified in Subpart H.

Applicability:

All new and existing industrial process cooling towers (IPCTs) which use chromium-based water treatment chemicals and are either a major source or are integral parts of a facility which is a major source (defined in 64.401).

40 CFR Part 63 - Subpart Q **National Emission Standards for Hazardous Air Pollutants for Industrial Process Cooling Towers**

Date of Applicability:

Existing IPCTs must comply with subpart Q no later than 18 months from September 8, 1994. New IPCTs that have initial startup before September 8, 1994 must comply by September 8, 1994. New IPCTs that have initial startup on or after September 8, 1994, must comply upon initial startup.

Affected Processes:

No owner/operator of an IPCT shall use chromium-based water treatment chemicals in any affected IPCT (63.402).

Monitoring Requirements:

No monitoring is required unless there is evidence to indicate that the IPCT is not in compliance with the requirements of 63.402.

Record Keeping:

Copies of initial notification and notification of compliance status are required to be kept onsite for at least 5 years as specified in 63.405(a).

Reporting Requirements (as per 63.405):

Initial notification, notification of compliance status (in accordance with Part 63, subpart A):
Table 1 of Subpart Q indicates general provisions applicability.

Applicability:

Owners or operators of stationary sources that have more than a threshold quantity of a regulated substance in a process, as determined under §68.115.

40 CFR Part 68

Chemical Accident Prevention Provision

Date of Applicability:

The latest of the following dates:

- June 21, 1999
- Three years after the date on which a regulated substance is first listed
- The date on which a regulated substance is first present above a threshold quantity

Applicable Program:

Program 1 - For five years prior to submission of the RMP, the process has not had an accidental release of a regulated substance that led to death, injury, or response or restoration activities for exposure to an environmental receptor, and the distance to a toxic or flammable endpoint for a worst-case release assessment is less than the distance to any public receptor, and emergency response procedures have been coordinated between the stationary source and local emergency planning and response organizations.

Program 2 - A covered process not subject to Program 1 or Program 3

Program 3 - A covered process, not subject to Program 1 and either; the process is in SIC code 2611, 2812, 1821, 2865, 2869, 2873, 2879, or 2911, or, the process is subject to the OSHA process safety management standard 29 CFR §1910.119.

General Requirements:

Submit a Risk Management Plan (RMP) with a registration that includes all covered processes.

Risk Management Plan Requirements: RMPs shall include:

- an executive summary describing elements of the RMP
- a single registration form covering all regulated substances
- worst-case release scenario information
- five-year accident history information
- emergency response program information
- certification statement
- regular review and updates to the RMP
- additional Programs 2 and 3 information.

Other Requirements:

- Maintain records for five years
- Information available to the public
- Additional permit requirements for facilities permitted pursuant to Parts 70 or 71.
- Provide access to implementing agency for RMP audits.

40 CFR Part 82

Protection of Stratospheric Ozone

Subpart A: Production and Consumption Controls

Subpart E: The Labelling of Products Using Ozone-Depleting Substances

Subpart F: Recycling and Emissions Reduction

Additional Program 1 Requirements:

- Analyze worst-case release scenarios, document public receptor is beyond endpoint, and submit
- Complete five year accident history for the process and submit
- Ensure that response actions coordinated with local agencies
- Certify as specified in §68.12(b)(4).

Additional Program 2 Requirements:

- Develop and implement a management system, assigning a qualified person with the overall responsibility for the program
- Conduct a hazard assessment
- Implement a Program 2 or Program 3 Prevention Program
- Develop and implement an emergency response program
- Submit the data on prevention program elements for Program 2 processes.

Additional Program 3 Requirements:

- Develop and implement a management system, assigning a qualified person with the overall responsibility for the program
- Conduct a hazard assessment
- Implement a Program 3 Prevention Program
- Develop and implement an emergency response program
- Submit the data on prevention program elements for Program 3 processes.

Applicability:

Any individual, corporate or government entity that produces, transforms, imports, or exports these controlled substances.

40 CFR PART 82	
REQUIREMENTS	EFFECTIVE DATE
<p>Subpart A: Production and Consumption Controls</p> <p>Prohibition on the production and consumption of any Class I substance in annual quantities greater than the relevant percentage specified in the regulations (based on quantity of substance produced in the baseline year)</p> <p>Prohibition on the production of all Class I substances</p> <p>Prohibition on the production of all Class II substances</p> <p>Reporting Requirements:</p> <p>Reports on production, imports, and exports of Class I and II substances</p> <p>Subpart E: The Labelling of Products Using Ozone-Depleting Substances</p> <p>Containers in which Class I and II refrigerants are stored or transported are required to be labelled with a warning stating that it contains a substance which harms public health and environment by destroying ozone in the upper atmosphere</p> <p>Subpart F: Recycling and Emissions Reduction</p> <p>Prohibition on knowingly venting ozone-depleting compounds used as refrigerants into the atmosphere during maintenance, service, repair, or disposal of air-conditioning or refrigeration equipment</p> <p>Technicians servicing air-conditioning and refrigeration equipment are required to evacuate refrigerant in the line according to prescribed guidelines</p>	<p>January 1 of each year specified in the regulations</p> <p>January 1, 2000 (January 1, 2002 for methyl chloroform)</p> <p>January 1, 2030</p> <p>Quarterly</p>
<p>Recovery and/or recycling equipment must be tested by an EPA-approved third-party testing organization</p> <p>Require repair of substantial leaks in industrial process refrigeration equipment (charge greater than 50 pounds).</p> <p>All persons who maintain, service, repair, or dispose of appliances are required to be certified.</p>	<p>All equipment sold after November 15, 1993</p> <p>Equipment manufactured prior to this date is grandfathered</p> <p>Within 30 days of recovery</p> <p>November 14, 1994</p>

40 CFR PART 82	
REQUIREMENTS	EFFECTIVE DATE
Persons servicing or disposing of air-conditioning and refrigeration equipment are required to certify that certified recovery and recycling equipment has been acquired and they are complying with the applicable requirements of 40 CFR Part 82, Subpart F.	August 12, 1993

Safe Drinking Water Act (SDWA)

The Safe Drinking Water Act (SDWA) mandates that EPA establish regulations to protect human health from contaminants in drinking water. The law authorizes EPA to develop national drinking water standards and to create a joint Federal/State system to ensure compliance with these standards. The SDWA also directs EPA to protect underground sources of drinking water through the control of underground injection of liquid wastes. The Public Water System Program (i.e., the National Primary and Secondary Drinking Water Regulations) and the Underground Injection Control (UIC) Program are two components of the SDWA that may be applicable to pharmaceutical manufacturing facilities. The requirements of the programs are summarized below.

Public Water System Program

Under the SDWA, EPA has established primary and secondary drinking water regulations designed to protect the public health. The primary drinking water regulations cover contaminants that have been determined to have adverse effects on human health or are enforceable by EPA or a State. The secondary drinking water regulations cover contaminants that affect the aesthetic quality of drinking water and are intended as guidelines that are not enforceable by EPA but a State can choose to enforce some or all of the secondary drinking water regulations. Most of the States have “primacy” for the program; that is, they have adopted the primary drinking water regulations and are responsible for implementing and enforcing the regulations. The States can develop regulations more stringent than the national drinking water regulations. The national drinking water regulations apply to public water systems. A public water system is defined as a system that either (1) has at least 15 service connections or (2) regularly serves an average of at least 25 individuals daily at least 60 days out of the year. There are three types of public water systems: community water systems, non-transient non-community water systems and transient non-community water systems. Facilities employing at least 25 people and regularly providing potable water from its private well, lake, river or reservoir to these same employees for over 6 months of the year would be classified as a non-transient non-community public water system.

National Primary Drinking Water Regulations have been established for 78 contaminants: 50 organics, 18 inorganics, 2 radionuclides, and 8 microbiologicals. For each contaminant, the national primary drinking water regulations establish

Safe Drinking Water Act

Public Water Supply Program SDWA-1
Underground Injection Control Program SDWA-2
SDWA Assessment Considerations . . . SDWA-3
SDWA Regulatory Requirements SDWA-4

Maximum Contaminant Level Goals (MCLGs) and Maximum Contaminant Levels (MCLs) or treatment techniques.

The National Primary Drinking Water Regulations also establish testing procedures, monitoring requirements such as minimum monitoring frequencies, record-keeping requirements, public notification requirements and requirements for routine reporting to the State or EPA. Specific analytical methods must be used and the analyses must be conducted by laboratories certified by EPA or the State. Some state programs require that the analyses be conducted by the State laboratory.

Monitoring requirements vary by contaminant, by source of supply, and by system size. The State customizes the sampling frequency to the local circumstances and may even waive sampling requirements for specific contaminants.

Underground Injection Control Program

The SDWA UIC program (40 CFR Parts 144-148) is a permit program that protects underground sources of drinking water through regulation of five different classes of injection wells. A 'well' is defined at 40 CFR §144.3 as a bored, drilled, or driven shaft, or a dug hole, whose depth is greater than the largest surface dimension. The five well classes are as follows:

- Class I:** Technologically sophisticated wells that inject large volumes of hazardous and non-hazardous wastes into deep isolated rock formations that are separated from the lowermost underground source of drinking water (USDW) by many layers of impermeable clay and rock.
- Class II:** Wells that inject fluids associated with oil and natural gas production. Most of the injected fluid is brine that is produced when oil and gas are extracted from the earth (about 10 barrels for every barrel of oil).
- Class III:** Wells that inject super-hot steam or water into mineral formations, which are then pumped to the surface and extracted. Generally, the fluid is treated and reinjected into the same formation. More than 50 percent of the salt and 80 percent of the uranium extraction in the United States is produced this way.
- Class IV:** Wells that inject hazardous or radioactive wastes into or above underground sources of drinking water. These wells are banned under the UIC program because they directly threaten the quality of underground sources of drinking water.

Class V: Wells that use injection practices not included in the other classes. Some Class V wells are technologically advanced wastewater disposal systems used by a variety of manufacturing facilities, but most are "low-tech" holes in the ground. Generally, these wells are shallow and depend upon gravity to drain or "inject" liquid waste into the ground. Their simple construction provides little or no protection against possible ground water contamination, so it is important to control what goes into them.

Class I and V UIC permitting programs are of significance to manufacturing facilities. The UIC permit program is primarily state-run, since EPA has authorized all but a few states. UIC permits include design, operating, inspection, and monitoring requirements. Operation of injection wells may also be authorized by rule (i.e., permit by rule). Wells used to inject hazardous waste must also comply with RCRA corrective action standards and must meet applicable RCRA LDR standards.

Any underground injection is unlawful unless authorized by a permit or a rule. Additionally, the construction of any well required to have a permit is also prohibited until issuance of that permit. All owners or operators are required to apply for a permit, even if authorized by rule, unless the authorization was for the life of the well.

Currently, there are limited Federal requirements for the injection into Class V wells. However, if injection into these wells could cause the water in the receiving USDW to violate primary drinking water regulations, then EPA or an authorized state could require the issuance of a permit that could include the substantive requirements of the UIC program (40 CFR §144.12(c)).

SDWA Assessment Considerations

Compliance evaluations should determine whether the facility has its own potable water supply and if so, whether the facility regularly provides this potable water to at least 25 of the same people at least six months of the year. If it is determined that the facility is subject to the national drinking water regulations, then the inspection team should evaluate whether the facility has conducted monitoring of required contaminants at required frequency. The inspector should verify that the facility is using an approved laboratory and approved tests and is maintaining the required records. The inspectors should confirm that the facility has notified employees of violations through continuous posting in conspicuous places in the workplace or through hand delivered or mailed written notices.

Compliance evaluations should determine if wastes are being injected at the site, and if so, if the facility is operating under a permit or by rule. If permitted, the inspection team should verify that all terms of the permit are being met. The inspection team should confirm that

wastes being injected are identified in the permit and no unpermitted wastes are injected. Also, the inspectors should evaluate well records and verify that the volume of waste being injected is within the limitations of the permit. If operating under rule, inspectors should verify that a permit application has been submitted in accordance with the Federal or State requirements unless the facility is authorized by rule to inject during the life of the well. If operating under permit by rule conditions, the inspectors should verify that the facility is complying with applicable regulations identified in 40 CFR Part 144, Subpart C.

SDWA Regulatory Requirements

The following section provides a summary of the principal regulations developed pursuant to the SDWA that may apply to the pharmaceutical manufacturing industry: 40 CFR Part 141 - National Primary Drinking Water Regulations; 40 CFR Part 143 - National Secondary Drinking Water Regulations; and 40 CFR Part 144 - Underground Injection Control Program.

Applicable Subparts:

Public water systems
classifications applicable to
pharmaceutical manufacturers:

40 CFR Part 141 **National Primary Drinking Water Regulations**

- **Community water system** - A public water system which serves at least 15 service connections used by year round residents or regularly serves at least 25 year-round residents.
- **Non-transient non-community water system** - A public water system that is not a community water system and that regularly serves at least 25 of the same persons over 6 months per year.

40 CFR PART 141	
REQUIREMENTS	EFFECTIVE DATE
Maximum Containment Levels Subpart B, G Maximum Containment Level Goals Subpart F Monitoring and Analytical Requirements Subpart C Treatment Techniques Subparts H, I Reporting Public Notification and Record Keeping Subpart D, H, I	All regulations in effect

Required Sampling and Testing Frequencies, §§141.21-141.30

TESTS	FREQUENCY (COMMUNITY SYSTEM)	FREQUENCY (NON-COMMUNITY)
Inorganics	<ul style="list-style-type: none">• Systems using surface water: every year• Systems using groundwater only: every 3 years	State option except for nitrate*
Organics: except THMs	<ul style="list-style-type: none">• Systems using surface water: every 3 years• Systems using groundwater only: state option	State option
Organics: THMs	<ul style="list-style-type: none">• Systems serving populations of 10,000 or more: 4 samples per quarter per plant	State option

TESTS	FREQUENCY (COMMUNITY SYSTEM)	FREQUENCY (NON-COMMUNITY)
Coliform bacteria**	<ul style="list-style-type: none"> Dependent on number of people served by the water system 	Same as community system unless only groundwater not under the influence is used and serves less than 1,000 people then 1 per quarter (for each quarter water is served to public)
Radiochemicals: natural	<ul style="list-style-type: none"> Systems using surface water: every 4 years (exceptions included in §141.26(a)(3)) Systems using groundwater only: every 4 years (exceptions included in §141.26(a)(3)) 	State option
Radiochemicals: man-made	<ul style="list-style-type: none"> System using surface water serving population greater than 100 000: every 4 years. All other systems: state option 	System using surface and/or groundwater: state option

* Although routine nitrate monitoring is established at state option, the initial monitoring is required and should have been completed by June 1979.

** Repeat sampling required if routine sampling is total coliform-positive.

Special Monitoring Requirements for Sodium and Corrosion (Community systems only)

TEST	FREQUENCY
<p>Sodium</p> <p>Corrosivity includes those characteristics known to indicate corrosivity:</p> <ul style="list-style-type: none"> pH Calcium hardness Total dissolved solids (TDS) Temperature Langelier Index 	<p>Systems using surface water: annually</p> <p>Systems using groundwater only: every 3 years</p> <p>Once unless additional monitoring required by state or EPA</p>

Record-Keeping Requirements [§§141.33 and 141.91]

RECORDS PERTAINING TO	TIME PERIOD
Bacteriological analyses	At least 5 years
Chemical analyses	At least 10 years
Actions taken to correct violations	At least 3 years after last action taken
Sanitary survey reports	At least 10 years
Variances or exemptions	At least 5 years following expiration
Lead and copper control	At least 12 years

Lab Reports Summary Requirements [§141.33]

SAMPLING INFORMATION	ANALYSIS INFORMATION
Date, place, and time of sampling	Date of analysis
Name of sample collector	Laboratory conducting analysis
Identification of sample:	Name of person responsible for analysis
<ul style="list-style-type: none"> Routine or check sample Raw or treated water 	Analytical method used
	Analysis results

Reporting Requirements for Check Sampling

CONTAMINANT	CHECK-SAMPLE REPORTING
Microbiological	Must report to state within 48 hours when any check sample confirms the presence of coliform bacteria.
Nitrate	Must report to state within 24 hours if check sampling confirms MCL has been exceeded
All others	Must be reported to the state within 10 days after the end of the month in which the sample was received.

MCL Violations

CONTAMINANT	VIOLATION
Inorganic chemicals (except nitrate) and organic chemicals (except THMs)	If average of results from all samples taken in year (if more than one sample) or average of initial sample and check sample exceeds MCL
Nitrate	If average of results from initial sample plus the check sample exceeds MCL
THMs	If average of results from present quarter plus those of 3 preceding quarters exceeds MCL*
Radionuclides (natural and man-made)	If average annual concentration exceeds MCL**
Microbiological (coliform testing): membrane filter and multiple-tube fermentation	If any of the MCLs are exceeded

* Quarter means a 3-month period. For convenience, calendar quarters are used.

** Based on individual analyses of 4 consecutive quarterly samples or a single analysis of an annual composite of 4 quarterly samples.

Public Notification Requirements, §141.32

VIOLATION OR CONDITION	REQUIRED TIMING			
	72 HOURS	14 DAYS	45 DAYS	3 MONTHS
Violation of an MCL, acute	3, 4, 5	2, 4, 5	1, 4, 5	1, 4, 5
Violation of an MCL, non-acute		2, 4, 5	1, 4, 5	1, 4, 5
Failure to monitor				2, 4, 5
Failure to follow compliance schedule				2, 4, 5
Failure to use approved testing procedure				2, 4, 5
System granted a variance or exemption				1, 4, 5

1 - Direct mail
4 - Hand delivery

2 - Local newspaper
5 - Continuous posting in conspicuous places

3 - By local radio and/or TV

Applicable Subparts:

These regulations are not Federally enforceable but are intended as guidelines for States.

40 CFR Part 143
National Secondary Drinking Water Regulations

40 CFR Part 143	
Component	Regulatory Recommendation
Standards	Secondary MCLs exist for 15 contaminants
Monitoring	Conducted at least as frequently as the monitoring performed for inorganic chemicals in the National Interim Primary Drinking Water Regulations and more frequently for parameters such as pH, color, and odor
Analytical Methods	pH, copper, and fluoride should be analyzed consistent with methods described in 40 CFR Part 141. Other contaminants should be analyzed using the procedures specified in 143.4(b).
Notification	Community water systems that exceed the secondary MCL for fluoride, but do not exceed the primary MCL, should notify (using the public notice provided in 143.5(b)) all billing units annually, all new billing units at the time service begins, and the state public health officer.

Applicable Subparts:

Well classifications applicable to pharmaceutical manufacturers:

40 CFR Part 144 **Underground Injection Control Program**

- **Class I - Wells used to inject hazardous or nonhazardous wastes beneath the lower most formation containing within one-quarter mile of the well-bore, an underground source of drinking water.**
Class V - Injection wells not included in other classes.

40 CFR PART 144	
REQUIREMENTS	EFFECTIVE DATE
<p>Any underground injection is prohibited unless authorized by permit or rule. Construction of any well required to have a permit is prohibited until the permit has been issued.</p> <p>Injection activity may not allow movement of fluid containing any contaminants into underground sources of drinking water if the presence of that contaminant may cause a violation of any primary drinking water regulation or adversely affect human health 40 CFR 144.12.</p> <p>Authorization by Rule Requirements:</p> <ul style="list-style-type: none">• Inventory information as specified in 40 CFR 144.26• 24-hour notification of noncompliance that may endanger health or the environment (Class I wells) as required in 40 CFR 144.28(b)• Plugging and abandonment plan (Class I wells) as required in .40 CFR 144.28(c).• Reports containing the information required in 40 CFR 144.28(h)(l) (Class I wells)• Notice of abandonment as required in 40 CFR 144.28(j)• Plugging and abandonment report as required in 40 CFR 144.28(k)	<p>One year after the date of approval or effective date of the UIC program for the State.</p> <p>Orally within 24 hours and written five days</p> <p>One year after the effective date of the UIC program in the State (EPA administered programs).</p> <p>Quarterly</p> <p>As specified by the Director</p> <p>Existing wells: No later than 4 years from approval or promulgation of UIC program.</p> <p>New wells: Reasonable time before construction is expected to begin</p>

40 CFR PART 144	
REQUIREMENTS	EFFECTIVE DATE
Authorization by Permit <ul style="list-style-type: none"> • All owners and operators (even those authorized by rule, unless authorized for life of the well) are required to submit a permit application containing the information in 40 CFR 144.31. 	

Resource Conservation and Recovery Act (RCRA)

The Resource Conservation and Recovery Act (RCRA) of 1976, which amended the Solid Waste Disposal Act of 1965, addresses hazardous (Subtitle C) and solid (Subtitle D) waste management activities. The Hazardous and Solid Waste Amendments (HSWA) of 1984 strengthened RCRA's waste management provisions, including adding a Subtitle I which governs Underground Storage Tanks (USTs). The goals and objectives of RCRA are to protect human health and the environment and to conserve valuable materials and energy resources. The applicable RCRA titles and the regulations and guidelines developed pursuant to RCRA are illustrated in Exhibit RCRA-1 and are discussed below.

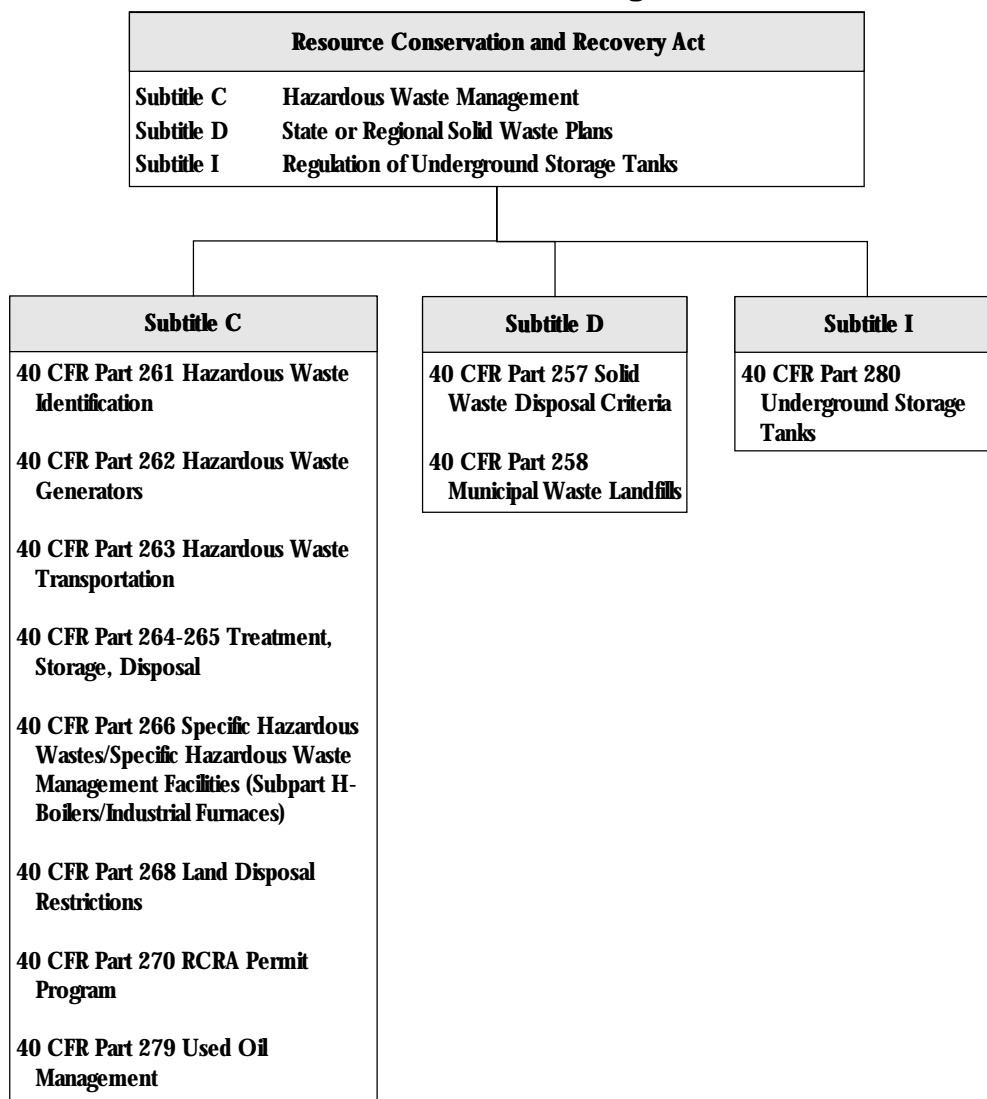
Regulations promulgated pursuant to Subtitle C of RCRA, at 40 CFR Parts 260-272, establish a "cradle-to-grave" system that governs hazardous wastes from the point of generation to treatment or disposal. As of 1996, 46 States are authorized to implement aspects of the RCRA program and may include requirements more stringent than Federal regulations in their authorized program. There are different levels of State authorization. States can be authorized (i.e., approval to implement a State-administered program) for the base RCRA program, or pre-HSWA RCRA requirements, for administering land disposal requirements, and for administering the RCRA corrective action program. Non-RCRA authorized states or territories (Alaska, Hawaii, Iowa, Puerto Rico and Wyoming) may also have state laws that address hazardous waste management requirements.

Subtitle D of RCRA sets up a framework for regulating non-hazardous solid wastes. Impacts from Subtitle D on a pharmaceutical facility may be direct, where the facility operates a solid waste incinerator or manages an on-site solid waste landfill, or indirect, coming into play as a result of a facility's use of an off-site solid waste disposal facility. Non-hazardous solid wastes are regulated through state solid waste management programs and are specific to each state. Typically, units such as solid waste landfills and non-hazardous waste incinerators are regulated through state-issued permits. Subtitle I regulates USTs that contain petroleum and hazardous substances. Regulations for USTs are promulgated at 40 CFR Part 280. Following is a summary of RCRA regulations applicable to the pharmaceutical manufacturing industry.

Resource Conservation and Recovery Act Requirements

Hazardous Waste Generation	RCRA-2
Hazardous Waste Transportation Regulations ...	RCRA-7
Hazardous Waste Treatment, Storage, and Disposal Regulations	RCRA-7
Land Disposal Restrictions	RCRA-8
Underground Storage Tank Regulations	RCRA-9
RCRA Assessment Considerations	RCRA-11
RCRA Regulatory Requirements	RCRA-12

Exhibit RCRA-1. RCRA Statutes and Regulatory Requirements for Pharmaceutical Manufacturing Facilities



Hazardous Waste Generation

Generators of hazardous waste are subject to requirements under 40 CFR Part 262. The determination of what material is a hazardous waste is the starting point of any RCRA compliance evaluation. Regulations for identification of hazardous wastes are detailed in 40 CFR Part 261. Under the Federal rules, to be a hazardous waste, a waste must: be a solid waste (as defined in 40 CFR §261.2); not be excluded from regulation as a hazardous waste under 40 CFR §261.4; and be a characteristic waste, a listed waste, a mixture of a solid waste and a listed waste, or a mixture of a solid waste and a characteristic waste that still exhibits that

characteristic. Also, a waste is hazardous if it is a mixture of soil or water and a listed waste, or a mixture of soil or water and a characteristic waste that still exhibits that characteristic.

A solid waste, by definition, is any discarded material—solid, liquid, or containerized gas—that is not excluded under the statute or regulations. Exclusions include hazardous waste mixed with domestic sewage, discharged as point source discharges regulated under the CWA and certain secondary materials that are reclaimed and reused in the original process or processes in which they were generated.

If a waste meets the definition of solid waste, it is considered hazardous if it exhibits one or more of four defined hazardous waste characteristics (see Exhibit RCRA-2), or is listed as a hazardous waste in 40 CFR Part 261 (see Exhibit RCRA-3). It is the generator's responsibility to determine whether a waste is hazardous. This determination must be based on test results or the generator's knowledge and familiarity with the waste. Generators may be subject to enforcement penalties for improperly determining that a waste is not hazardous.

Exhibit RCRA-2. Characteristic Hazardous Wastes

Ignitability	Flashpoint below 140 °F §261.21
Corrosivity	Liquids with a pH equal to or below 2 or equal to or above 12.5 or which corrode steel at a specified rate §261.22
Reactivity	Reacts violently with water or other substances to create toxic gases §261.23
Toxicity	A waste that leaches specified amounts of metals, pesticides, or organic chemicals using the Toxicity Characteristic Leaching Procedure (TCLP) §261.24

Exhibit RCRA-3. Listed Hazardous Wastes

"F" Wastes	Hazardous wastes from nonspecific sources §261.31
"K" Wastes	Hazardous wastes from specific sources §261.32
"U" Wastes	Hazardous wastes from discarded commercial chemical products, off-specification species, container residues, and spill residues §261.34
"P" Wastes	Acutely hazardous wastes from discarded commercial chemical products, off-specification species, container residues, and spill residues §261.33

If the waste is not found on any of these lists, it is not hazardous, although it may be listed on a State hazardous waste list.

Secondary materials generated by the pharmaceutical industry may be classified as solid wastes and potentially hazardous wastes where they are recycled in certain ways (e.g., used in a manner constituting disposal, burned for energy recovery, reclaimed, or accumulated speculatively). Such materials are considered accumulated speculatively where the material is stored with less than 75 percent recycled within one calendar year. Under 40 CFR

261(c)(8), persons accumulating secondary materials prior to recycling must be able to show 1) the material is potentially recyclable; 2) they have a feasible means of recycling such material; and 3) during the calendar year the amount of material recycled or transferred to a different site for recycling equals at least 75 percent by weight or volume of the amount of material accumulated at the beginning of the period. The 75 percent requirement is to be applied to each material of the same type that is recycled in the same way. Materials accumulating in units exempt from regulation under § 261.4(c) are not included in making the calculation. And commercial chemical products being speculatively accumulated are not regulated as solid wastes.

Hazardous wastes that are recycled are subject to the requirements for generators, transporters, and storage facilities as identified in 40 CFR §261.6(b) and (c), except as excluded in 40 CFR §261.6(a)(3). In addition, §261.6(a)(2) identifies recycled materials that are only subject to Parts 266 (recycling regulations), 270 (permits), and 124 (NPDES permits). This includes recyclable materials such as those that are used in a manner constituting disposal, hazardous wastes burned for energy recovery in boilers and industrial furnaces, and used oil burned for energy recovery. Any facility that stores recyclable materials before they are recycled, except those materials excluded in 40 CFR §261.6(a), must comply with applicable storage requirements of 40 CFR Parts 264 and 265.

The regulations also establish requirements for residues of hazardous waste in empty containers. Specifically, 40 CFR §261.7 establishes that empty containers and inner liners from an empty container are not subject to the hazardous waste regulations, provided that all wastes have been removed using the practices commonly employed to remove materials from that type of container, no more than one inch of residue remains in the container or inner liner, or no more than 3 percent by weight of the total capacity (or 0.3 percent for larger containers) remains in the container or inner liner. Containers that have held compressed gas are considered empty when the pressure approaches atmospheric. For acute hazardous wastes, additional measures are required.

Generators of hazardous wastes are the first link in the cradle-to-grave chain of hazardous waste management. Under RCRA, there are three categories of hazardous waste generators: large quantity generators (LQGs), small quantity generators (SQGs), and conditionally exempt small quantity generators (CESQGs). The determination of a generator's applicable category is summarized in Exhibit RCRA-4.

CESQGs must only comply with the Part 262 generator regulations as established at 40 CFR §261.5. Specifically, CESQGs must identify the waste to determine if it is a hazardous waste, accumulate less than 1,000 kilograms of hazardous waste at any time, treat or dispose of the waste on-site, or ensure that the waste is sent to a permitted facility or a recycling facility. The requirements CESQG are exempt from include, but are not limited to, the following:

- **Manifest requirement**
- **Exception report—when generator does not receive a copy of the signed manifest from the TSD facility**
- **Biennial/annual report**
- **Personnel training**
- **Contingency plan**
- **EPA ID number**
- **Storage requirements—no need to meet technical requirements under part 264 or 265 for containers or tanks.**

However, many transporters will not accept wastes from a generator without an EPA ID number or manifest.

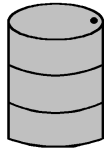
CESQGs that exceed the 100 kilograms per month hazardous waste generation cutoff are subject to SQG provisions. CESQGs that exceed the 1 kilogram per month of acutely hazardous waste generation cutoff are subject to the LQG provisions. Note that some States do not have CESQG exemptions (i.e., all generators must meet the same requirements).

All SQGs and LQGs must comply with requirements as described in 40 CFR Part 262. Standards for generators establish responsibilities including obtaining an EPA identification number, preparing hazardous waste manifests, ensuring proper packaging and labeling, meeting standards for waste accumulation units, and recordkeeping and reporting requirements. This Part also identifies requirements for generators that are importing or exporting hazardous wastes into or out of the country.

Generators can accumulate hazardous waste for up to 90 days (180 days for SQGs) without obtaining a storage permit provided that the facility complies with specific conditions in 40 CFR §262.34, including applicable management standards for containers, tanks, and drip pads. Each accumulation container must include a "Hazardous Waste" label, identify the date upon which accumulation began, and the facility must comply with 40 CFR Part 265, Subpart C (Preparedness and Prevention). Additionally for LQGs, Subpart D (Contingency Plan and Emergency Procedures), and with 40 CFR §265.16 (Personnel Training). SQGs have less stringent requirements for accumulation than LQGs as identified in 40 CFR §262.34(d) and (e).

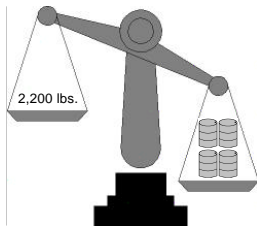
Exhibit RCRA-4. Categories of Hazardous Waste Generators

KEY:



= 1 barrel = about 200 kilograms of hazardous waste which is about 55 gallons

YOU ARE A LARGE QUANTITY GENERATOR If ...



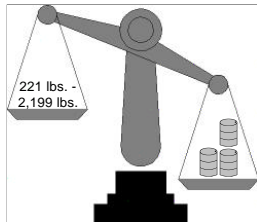
In one calendar month you ...

- generate 2,200 pounds or more of hazardous waste or
- generate 2,200 pounds or more of spill cleanup debris containing hazardous waste or
- generate more than 2.2 pounds of acutely hazardous waste or
- generate more than 220 pounds of spill cleanup debris containing an acutely hazardous waste or

At any time you ...

- accumulate more than 2.2 pounds of acutely hazardous waste on-site

YOU ARE A SMALL QUANTITY GENERATOR If ...



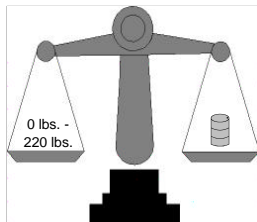
In one calendar month you ...

- generate more than 220 pounds and less than 2,200 pounds of hazardous waste or
- generate more than 220 pounds and less than 2,200 pounds of spill cleanup debris containing hazardous waste or

At any time you ...

- accumulate more than 2,200 pounds of acutely hazardous waste on-site

YOU ARE A CONDITIONALLY EXEMPT SMALL QUANTITY GENERATOR If ...



In one calendar month you ...

- generate 2.2 pounds or less of acutely hazardous waste or
- generate 220 pounds or less of hazardous waste or
- generate 220 pounds or less of spill cleanup debris containing hazardous waste or

At any time you ...

- accumulate up to 2.2 pounds of hazardous waste on-site

Hazardous Waste Transportation Regulations

Facilities that transport hazardous wastes off-site, where these wastes are required to be manifested pursuant to 40 CFR Part 262, must comply with transporter requirements established in 40 CFR Part 263. Hazardous waste transportation requirements, the middle link in the "cradle-to-grave" requirements of RCRA, require that the transporter obtain an EPA identification number, and specify manifesting and recordkeeping requirements, including specific conditions for shipment by rail or water. It is important to note that a transporter that stores wastes at an off-site location for more than 10 days must comply with Parts 264, 265, 268, and 270 for storage of those wastes. Subpart C of Part 263 establishes response requirements for discharges of hazardous wastes during transport.

Hazardous Waste Treatment, Storage, and Disposal Regulations

Any person owning or operating a facility that treats, stores, or disposes of hazardous waste is considered to be an owner/operator of a treatment, storage, or disposal (TSD) facility and is subject to requirements identified in 40 CFR Parts 264 and 265. Treatment, storage, and disposal facilities (TSDFs) are the last link in the cradle-to-grave regulation of RCRA. All TSDFs are required to obtain an operating permit and abide by TSD regulations. The TSD regulations establish design and operating criteria as well as performance standards that owners and operators must meet to protect human health and the environment. Because TSDs involve many different types of units, these regulations are far more extensive than those just described for generators and transporters.

The RCRA TSD regulations include both administrative and technical requirements. The regulations identify administrative requirements such as the applicability of the requirements, general facility standards, preparedness and prevention, contingency plans and emergency procedures, and manifesting, reporting, and recordkeeping. Technical requirements may address ground water monitoring, closure/post-closure, financial requirements, and standards related to the different types of waste management units. Specifically, the regulations identify requirements for containers, tanks, surface impoundments, waste piles, and treatment, landfills, incinerators, waste treatment, underground injection, and miscellaneous units. Also, RCRA TSD regulations identify air emission requirements for process vents, equipment leaks, and units that store hazardous wastes with high volatile organic concentrations from specific operations related to the managing and recycling of hazardous waste.

EPA's hazardous waste permitting program is established at 40 CFR Part 270. New TSDFs requiring a permit must submit a two part permit application. Part A is a short, standard form that collects general information about the facility, while Part B of the application is much more extensive and requires the facility to supply detailed and highly technical information. This submission must be made at least 180 days prior to the date on which physical construction is expected to start. Once issued, RCRA permits are valid for up to 10 years.

TSDs fall into two categories: interim status facilities and permitted facilities. Interim status regulations (40 CFR Part 265) apply to facilities that are operating under a Part A permit while their Part B permit application is being reviewed. Any facility that is in existence on the effective date of statutory or regulatory amendments under RCRA that render the facility subject to permitting requirements qualifies for interim status, provided that the facility notifies EPA of hazardous waste activity and complies with application requirements of 40 CFR §270.10. Interim status standards must be met until a Part B permit is issued. TSD permit standards (40 CFR Part 264) are facility-specific performance standards and design and operating requirements that are incorporated into a TSD permit. Permit writers use the standard permit language established in 40 CFR Part 264 to set facility-specific conditions. TSD permits can be extremely complex and may be several hundred pages in length. As such, an evaluation of specific permit conditions must be made at pharmaceutical manufacturing facilities operating under a RCRA TSD permit.

Land Disposal Restrictions

Under the Land Disposal Restriction (LDR) regulations (40 CFR Part 268), hazardous wastes are largely prohibited from land disposal. Once prohibited, the statute provides two options: comply with a specified treatment standard or dispose of the waste in a “no migration unit.” Land disposal includes any placement of hazardous waste into a landfill, land treatment unit, waste pile, inject well, salt dome or salt bed formation, underground mine or cave or surface impoundment. Restricted hazardous wastes may be land disposed only if certain treatment standards are met or if waste extract or waste treatment residue concentrations are met, as specified in 40 CFR §§268.41-43. Generators of wastes subject to the LDRs must provide notification of such to the designated TSD facility to ensure proper treatment prior to disposal. Facilities that generate less than 100 kilograms of non-acute hazardous waste or less than one kilogram of acute hazardous waste per month are not subject to the LDRs. The LDRs allow wastes which would otherwise be prohibited from land disposal to be treated in surface impoundments, provided that specific conditions are met as outlined in 40 CFR §268.4. Facilities may petition EPA for extensions to the effective date of LDRs in certain instances as identified in 40 CFR §268.5.

The Land Disposal Restrictions also specify that for certain characteristic wastes managed in non-Clean Water Act (CWA) wastewater treatment systems, non-CWA equivalent systems or non-Class I injection wells, the underlying hazardous constituents reasonably expected to be present in the waste at the point of generation should be treated as well as the hazardous characteristic. For wastes that are characteristic for organics (i.e., D018-D043), this requirement applies to both wastewaters and non-wastewaters. Underlying hazardous constituents include all those constituents listed in 40 CFR 268.48 (Universal Treatment Standards).

The LDRs prohibit the use of dilution as a substitute for treatment to meet the LDRs. However, wastes that are hazardous only because they exhibit a characteristic and that are treated in a treatment system which treats wastes and subsequently discharges these wastes pursuant to a CWA permit are exempt from LDRs provided that the characteristic is removed prior to management in a land based unit. Exhibit RCRA-5 provides a decision tree for making the determination as to whether dilution of a waste is permissible. Storage of hazardous wastes restricted from land disposal under Part 268 Subpart C is prohibited, unless certain conditions are met as identified in 40 CFR §268.50.

Underground Storage Tank Regulations

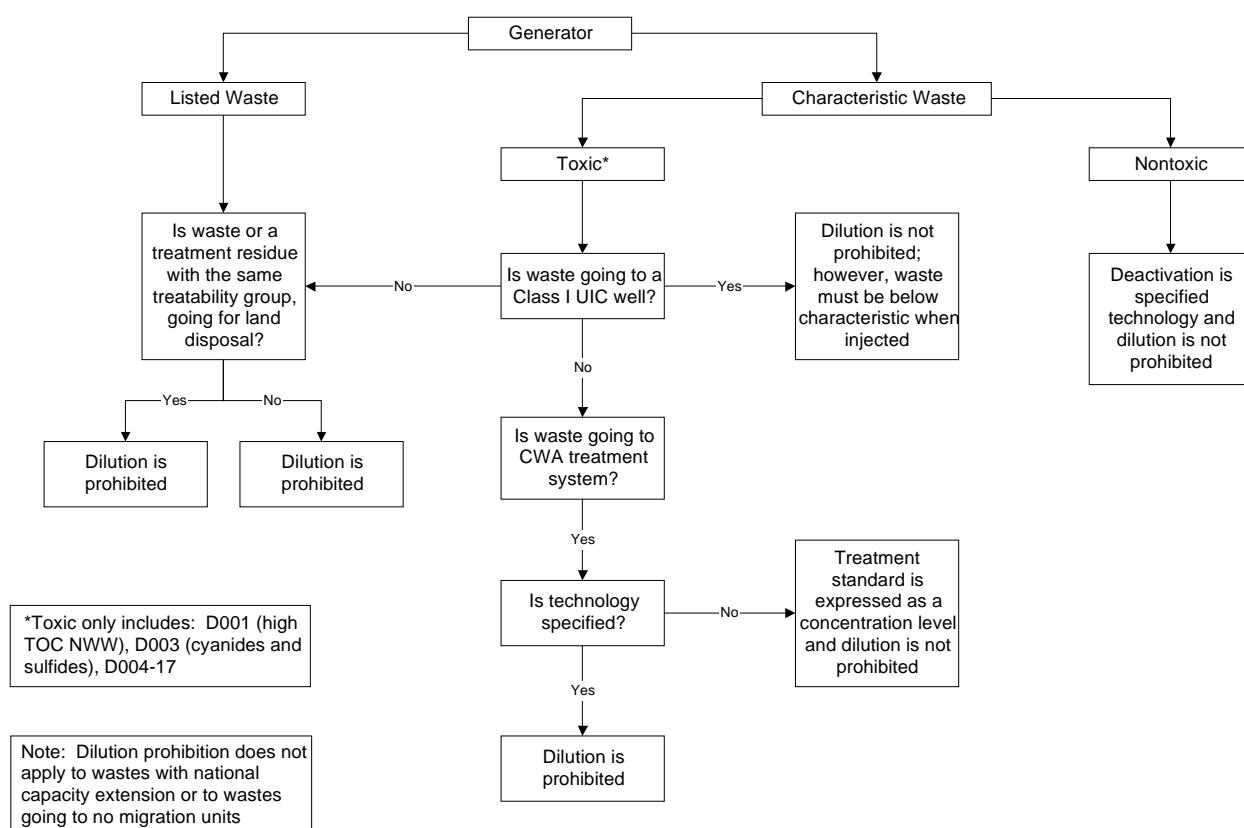
Underground storage tanks (USTs) containing petroleum and hazardous substances are regulated under 40 CFR Part 280. Federal, state, and local agencies are or may be involved in regulating USTs. The statute provides EPA with the authority to develop and enforce the UST program, but states have discretionary authority to develop their own UST regulatory program as long as the program is no less stringent than the Federal program. Local agencies may also implement UST provisions through local ordinances.

An underground storage tank is one that stores "regulated substances" and that has at least 10 percent of its volume below the surface of the ground, including piping connected to the tank. Regulated substances include hazardous substances regulated under CERCLA (above de minimis concentrations) and any petroleum products that are liquid at standard conditions. Regulated substances do not include hazardous wastes. As identified in 40 CFR §280.10(b)(1), underground tanks containing hazardous waste are not subject to 40 CFR Part 280 requirements. Rather, underground tanks containing hazardous wastes are subject to RCRA requirements, as appropriate.

Exclusions to the UST regulations include tanks such as for heating oil used primarily for space heating on the premises where the tank is stored, flow-through process tanks, any wastewater treatment tank system regulated under the CWA, tanks less than 110 gallons in capacity, spill or overflow containment systems that are expeditiously emptied after use, storm water and wastewater collection systems, and tanks situated on or above the floor of underground areas such as basements, shafts, and tunnels.

The regulations at 40 CFR Part 280 include conditions for design, construction, operation, installation, and notification; general operating requirements; release detection; release response, investigation, and confirmation; release reporting and corrective action; out-of-service UST systems and closures; and financial responsibility.

Exhibit RCRA-5. LDR Dilution Decision Tree



The UST program requires that by December 22, 1998, all existing USTs must add spill, overfill, and corrosion protection, close the existing UST; or replace the existing UST with a new UST. Spill protection is defined to include catchment basins to contain spills from delivery hoses. Overfill protection requires either an automatic shutoff valve, overfill alarms, or ball float valves. Corrosion protection requires that existing tanks match one of the following tank conditions and one of the piping conditions:

- ▶ **Tanks**
 - Steel tank has corrosion-resistant coating AND cathodic protection
 - Tank made of noncorrodible material
 - Steel tank clad with noncorrodible material or tank enclosed in noncorrodible material
 - Uncoated steel tank has cathodic protection system
 - Uncoated steel tank has interior lined with noncorrodible material
 - Uncoated steel tank has cathodic protection AND interior lined with noncorrodible material

- ▶ **Piping**
 - **Uncoated steel piping has cathodic protection**
 - **Steel piping has a corrosion-resistant coating AND cathodic protection**
 - **Piping made of (or enclosed in) noncorrodible material**

New USTs must have a suitable dielectric coating in addition to cathodic protection. Also, new USTs must be installed in accordance with a code of practice and in accordance with the manufacturer's instructions. Installation of new USTs must also be certified. Any facility which brings an UST into use after May 8, 1986, must submit the Notification Form prescribed in Appendix I of Part 280 (or a comparable state form) within 30 days of bringing the UST into use. This form must be submitted to the state or local agency or department designated in Appendix II of Part 280.

RCRA Compliance Assessment Considerations

The key components of a RCRA assessment are knowledge of the facility, a document review, and an assessment plan.

A RCRA self-assessment requires familiarity with what hazardous wastes are generated at the pharmaceutical manufacturing facility and how these wastes are managed. Pharmaceutical manufacturing facility operations can be exceedingly complex and varied, so a knowledge of each operation is necessary.

One source of information for determining compliance with RCRA requirements is a document review. Useful documents to review include facility maps and blueprints; aerial photographs; plant organization charts; piping and instrumentation diagrams (P&IDs); operating or procedure manuals; information about emission points, waste streams, or monitoring results; the daily operating log; company spill reports; permit applications; TRI reports; annual/biannual operating reports; and documents prepared for environmental activities such as siting a facility or remedial activity.

Before conducting an assessment, the assessor should draw up a Plan that traces material flows through the plant. The Plan should indicate whether samples will be necessary to determine if a particular waste stream is hazardous or if a release of hazardous material has occurred. In addition, appropriate reports should be prepared as required, for example, Quality Assurance/Quality Compliance Plans. Also, the Plan should reflect any special considerations set forth in the facility permit or any consent decree or agency findings and orders.

EPA has published various RCRA Inspection Checklists which are useful as guidance and as a framework for a Plan. For example, checklists are available that list requirements from RCRA

regulations for generators of hazardous waste, closure and post-closure plans and requirements, and land disposal requirements for generators.

Assessing compliance with RCRA paperwork and administrative requirements is as important as assessing compliance with waste management requirements. Administrative and paperwork requirements include keeping a daily log of facility operations, submitting an annual/biannual operating report to the regulatory agency, manifest requirements, waste analysis plans, certifications, having a contingency plan on file and procedures in place to implement the plan, conducting an adequate training program, and implementing adequate plant security.

During the actual assessment, the evaluation team should sit down with plant operations personnel and discuss plant organization and site operations, identifying and verifying major facility processes, preparedness and prevention measures, safety procedures that are observed and that need to be observed during the visual inspection, descriptions and locations of special equipment, and training programs.

RCRA Regulatory Requirements

The following sections provide summaries of the principal regulations developed pursuant to RCRA that may apply to the pharmaceutical manufacturing industry. The section includes:

- **40 CFR §§261.5 and 262.34 - Generator Classifications and Requirements**
- **40 CFR Part 262 - Hazardous Waste Generator Requirements**
- **40 CFR Part 263 - Hazardous Waste Transporter Requirements**
- **40 CFR Part 264 and 265 - Hazardous Waste Treatment Storage and Disposal**
- **40 CFR Part 268 - Land Disposal Restrictions**
- **40 CFR Part 280 - Underground Storage Tanks (UST)**

40 CFR Part 261.5 and 262.34

Generator Classifications and Requirements

Conditionally Exempt Small Quantity Generators (CESQG)

REQUIREMENTS	AFFECTED FACILITY
<ul style="list-style-type: none"> • Make hazardous waste determination under §262.11 • Waste must be managed and disposed in a hazardous waste facility, or a landfill or other facility approved by the State for industrial or municipal wastes • Must comply with §261.5(g) to be excluded from requirements under parts 262 through 266, 268, and 270. 	<ul style="list-style-type: none"> • Generate less than 100 kg/month (220 lbs/month) of hazardous waste, or • Generate less than 1 kg/month (2.2 lbs/month) of acute hazardous waste, or • Accumulate up to 1,000 kg (2,200 lbs) of hazardous waste onsite at any time

Small Quantity Generator (SQG)

REQUIREMENTS	AFFECTED FACILITY
<ul style="list-style-type: none"> • Subject to regulation under parts 262 through 266, 268, and 270. • Special requirements under §265.201 for accumulating hazardous waste in tanks. • May not accumulate more than 6,000 kg of hazardous waste at any time. • May not accumulate hazardous waste onsite for longer than 180 days (270 days if waste must be transported over 200 miles to hazardous waste facility), otherwise hazardous waste storage permit required. 	<ul style="list-style-type: none"> • Generate more than 100 kg/month (220 lbs/month) of hazardous waste and less than 1,000 kg/month (2,200 lbs/month) of hazardous waste, or • Accumulate more than 1,000 kg (2,200 lbs), but less than 6,000 kg of hazardous waste at any time

Large Quantity Generator (LQG)

REQUIREMENTS	AFFECTED FACILITY
<ul style="list-style-type: none">• Subject to regulation under parts 262 through 266, 268, and 270.• May not store hazardous waste onsite for more than 90 days, otherwise hazardous waste storage permit required.	<ul style="list-style-type: none">• Generate more than 1,000 kg/month (2,200 lbs/month) of hazardous waste, or• Generate more than 1 kg/month (2.2 lbs/month) of acutely hazardous waste, or• Generate more than 100 kg/month (220 lbs/month) of spill cleanup debris containing an acutely hazardous waste, or• Accumulate more than 1kg (2.2 lbs) of acutely hazardous waste at any time

40 CFR Part 262

Hazardous Waste Generator Requirements

40 CFR PART 262 - HAZARDOUS WASTE GENERATOR REQUIREMENTS		
REQUIREMENTS	DESCRIPTION	AFFECTED FACILITY
EPA ID Number §262.12	<ul style="list-style-type: none"> Cannot treat, store dispose of or transport hazardous waste without EPA ID Number 	LQG or SQG that transports, or offers for transportation, hazardous waste for offsite treatment, storage or disposal
Subpart B - Manifest Requirements §§262.20-260.33	<ul style="list-style-type: none"> Cannot offer hazardous waste to transporter or to treatment, storage, or disposal facilities that do not have an EPA ID Number 	
Subpart C - Pre-transport Requirements §§262.30-262.34	<ul style="list-style-type: none"> Must complete and sign EPA form 8700-22 or 8700-22A for each shipment of hazardous waste Must label and package hazardous waste in accordance with DOT regulations (49 CFR parts 172, 173, 178, 179) prior to transport Accumulation in units that comply with Subpart I of 40 CFR 265 (containers), or Subpart J of 40 CFR part 265 (tanks) 	
		SQGs allowed up to 180 (or 270) days for accumulating hazardous waste without a storage permit

40 CFR PART 262 - HAZARDOUS WASTE GENERATOR REQUIREMENTS		
REQUIREMENTS	DESCRIPTION	AFFECTED FACILITY
<p>Subpart D - Record keeping and Reporting §§262.40-262.44</p> <p>Subpart E - Exports of Hazardous Waste §§262.50-262.57</p>	<ul style="list-style-type: none"> • Accumulation in units that comply with air emission standards identified in 40 CFR 265 Subparts AA (process vents), BB (equipment leaks) and CC (tanks, surface impoundments and containers) and with Subpart DD (containment buildings) • May accumulate wastes up to 90 days without storage permit • Must develop and maintain a contingency plan for storing wastes on-site • Maintain copies of manifest for three years • Must prepare and submit Biennial Report • Must file exception report if manifests not received by designated facility within 35 days (LQG) or 60 days (SQG) • Notify EPA 60 days before shipment • Must confirm waste receipts or file an exception report • Must file a Summary Report of Foreign Activity on March 1 of each year 	<p>SQG exempt from biennial reporting requirements</p>
Subpart F - Imports of Hazardous Waste §262.60	<ul style="list-style-type: none"> • Must prepare manifest that identifies foreign generator and importer 	

40 CFR PART 262 - HAZARDOUS WASTE GENERATOR REQUIREMENTS		
REQUIREMENTS	DESCRIPTION	AFFECTED FACILITY
	<ul style="list-style-type: none"> • Must comply with all other generator standards in 40 CFR Part 262 	

40 CFR Part 263

Hazardous Waste Transporter Requirements

40 CFR PART 263 - HAZARDOUS WASTE TRANSPORTER REQUIREMENTS		
REQUIREMENTS	DESCRIPTION	AFFECTED FACILITY
EPA ID Number §263.11	<ul style="list-style-type: none">• Must obtain an EPA ID Number in order to transport hazardous waste	Persons who transport hazardous waste within the U.S. if manifest is required under 40 CFR §262.
Transfer Facility Requirements §263.12	<ul style="list-style-type: none">• May store manifested shipments for ten days or less, otherwise subject to hazardous waste storage requirements under parts 264, 265, 268, and 270	
Manifest and Record Keeping Requirements §263.20	<ul style="list-style-type: none">• Cannot receive a waste shipment unless accompanied by a hazardous waste manifest	
Hazardous Waste Discharges §263.30	<ul style="list-style-type: none">• Take appropriate action• Notify proper authorities	

40 CFR Part 264 and 265
Hazardous Waste Treatment, Storage, and Disposal

40 CFR PART 264 - FACILITY REQUIREMENTS (PART 265 INTERIM STATUS STANDARDS ARE SIMILAR BUT NOT IDENTICAL)		
REQUIREMENTS	DESCRIPTION	AFFECTED FACILITY
General Facility Requirements (Subpart B) Identification Number §264.11 Required Notices §264.12 General Facility Management Plans §§264.13-264.19	<ul style="list-style-type: none"> • Must obtain an EPA ID Number in order to treat, store, or dispose of hazardous waste • Must notify Regional Administrator of receipt of a hazardous waste from foreign source • Must notify generator that the facility receiving the waste has the proper permits • General Waste Analysis §264.13 • Security §264.14 • General Inspection Requirements §264.15 • Personnel Training §264.16 • General Requirements for I, C, R wastes §264.17 • Location Standards §264.18 • Construction Quality Assurance Program §264.19 	Facilities that treat, store or dispose of hazardous waste

40 CFR PART 264 - FACILITY REQUIREMENTS (PART 265 INTERIM STATUS STANDARDS ARE SIMILAR BUT NOT IDENTICAL)		
REQUIREMENTS	DESCRIPTION	AFFECTED FACILITY
Preparedness and Prevention (Subpart C) Contingency Plan and Emergency Procedures (Subpart D) Manifest System, Record keeping/Reporting (Subpart E) Releases from Solid Waste Management Units (Subpart F)	<ul style="list-style-type: none"> • Must be equipped with communications and alarm systems, fire control equipment, spill control equipment, decontamination equipment, adequate water supply and distribution system • Must make arrangements with local authorities for the event of an emergency • Must develop and follow written contingency plan to minimize hazardous from fires, explosions and releases • Must maintain a written operating record • Must comply with hazardous waste manifest requirements • Must submit a biennial report • Must submit Unmanifested Waste Report within 15 days of receiving hazardous waste without an accompanying manifest • Must implement a groundwater program capable of determining the facility's impact on ground water quality • Groundwater monitoring system • Develop and follow a ground-water sampling and analysis plan 	Owner/operator of a surface impoundment, landfill or land treatment facility used to manage hazardous waste

40 CFR PART 264 - FACILITY REQUIREMENTS (PART 265 INTERIM STATUS STANDARDS ARE SIMILAR BUT NOT IDENTICAL)		
REQUIREMENTS	DESCRIPTION	AFFECTED FACILITY
Closure and Post-Closure (Subpart G)	<ul style="list-style-type: none"> • Must develop and submit a written closure plan as part of the permit application under 40 CFR Part 270 	
Financial Requirements (Subpart H)	<ul style="list-style-type: none"> • Must have detailed written estimate of the cost of closing the facility under the closure plan • Must establish financial assurance by selecting appropriate options 	

**40 CFR Part 264 and 265
Hazardous Waste Treatment, Storage and
Disposal - Unit Specific Standards**

40 CFR PART 264 AND 265 UNIT SPECIFIC STANDARDS	
REQUIREMENTS	AFFECTED FACILITY
Containers (Subpart I)	Facilities that treat, store, or dispose of hazardous wastes in containers
Tank Systems (Subpart J)	Facilities that treat, store or dispose of hazardous wastes in tanks
Surface Impoundments (Subpart K)	Facilities that treat, store, or dispose of hazardous wastes in surface impoundments
Waste Piles (Subpart L)	Facilities that treat, store, or dispose of hazardous wastes in piles
Land Treatment (Subpart M)	Facilities that treat or dispose of hazardous wastes in land treatment units
Landfills (Subpart N)	Facilities that dispose of hazardous waste in landfills
Incinerators (Subpart O)	Facilities that treat or dispose of hazardous wastes in incinerators
Drip Pads (Subpart W)	Facilities that treat, store, or dispose of hazardous waste on drip pads.
Miscellaneous (Subpart X)	Facilities that treat, store or dispose of hazardous wastes in units not identified in 40 CFR Parts 264/265
Air Emission Standards for Process Vents (Subpart AA)	Facilities subject to RCRA permitting that have distillation, fractionation, thin-film evaporation, solvent extraction, or air/stream stripping operations that manage wastes with organic concentrations of at least 10 ppmw. (See §264.1030)
Air Emission Standards for Equipment Leaks (Subpart BB)	Facilities with equipment, regardless of process, that manage hazardous wastes in units which are subject to permitting under 40 CFR Part 270 and recycling units located at facilities subject to permitting (See §264.1050). Units that manage less than ten percent organics by weight require only record keeping.

40 CFR PART 264 AND 265 UNIT SPECIFIC STANDARDS	
REQUIREMENTS	AFFECTED FACILITY
Air Emissions Standards for Tanks, Surface Impoundments, and Containers (Subpart CC)	<p>Facilities that treat, store, or dispose of hazardous waste in tanks, surface impoundments, or containers subject to subparts J, K, or I, respectively.</p> <p>Certain units may not be subject to subpart CC if criteria under §§264.1080 and 264.1082 are met.</p>
Containment Buildings (Subpart DD)	<p>Facilities that treat or store hazardous wastes in containment buildings are required to meet certain design and operating standards.</p>

40 CFR Part 268

Land Disposal Restrictions - Certification and Notification

40 CFR PART 268 - GENERATOR - CERTIFICATION AND NOTIFICATION		
REQUIREMENTS	DESCRIPTION	AFFECTED FACILITY
Waste Analysis and Record keeping for Generators §268.7(a)	<ul style="list-style-type: none">• Must determine if waste is restricted from land disposal• If waste does not meet treatment standards in §268 Subpart D, must notify treatment or storage facility receiving waste• If waste meets treatment standards §268 Subpart D, must submit notification, certification, and supporting information to treatment, storage, or disposal facility receiving the waste• If accumulating and treating restricted wastes onsite, must develop waste analysis plan and file with Administrator or authorized State• Maintain copies of records, certifications, and notices for five years	LQGs and SQGs

40 CFR 268 - TREATMENT AND DISPOSAL - CERTIFICATION AND NOTIFICATION		
REQUIREMENTS	DESCRIPTION	AFFECTED FACILITY
Waste Analysis and Record Keeping for Treatment Facilities §268.7(b)	<ul style="list-style-type: none"> • Must test waste in accordance with waste analysis plan • Must submit notification and certification to land disposal facility receiving the waste 	Facilities that treat hazardous wastes subject to LDRs
Waste Analysis and Record Keeping for Disposal Facilities §268.7(c)	<ul style="list-style-type: none"> • Must maintain copies of all notices and certifications specified in §268.7(a) and (b) • Must test waste in accordance with waste analysis plan to determine if the treatment standards have been met 	Disposal Facilities

40 CFR Part 280

Underground Storage Tanks (UST)

40 CFR PART 280 - UNDERGROUND STORAGE TANK REQUIREMENTS		
REQUIREMENTS	DESCRIPTION	AFFECTED FACILITY
Design, Construction, Installation, and Notification (Subpart B)	<ul style="list-style-type: none"> • New USTs (installed after December 1988) must meet performance standards detailed in 40 CFR §280.20 • All existing UST systems (installed before December 1988) must be upgraded to meet standards detailed in 40 CFR §280.21 by December 1998 • Notify State and/or local agencies upon the installation and use of new UST systems (40 CFR §280.22) 	All owners and operators of underground storage tank systems as defined in 40 CFR §280.12 (See §280.10 (b-d) for exceptions)
General Operating Requirements (Subpart C)	<ul style="list-style-type: none"> • Must ensure the prevention of releases through spill and overfill control, proper corrosion protection, use of compatible materials, and proper and appropriate repairs to the UST system • Reporting requirements include notification, reports of all releases (suspected and confirmed), corrective action, and permanent change in service or closure. • Record keeping requirements include documentation of corrosion controls, UST system repairs, release detection compliance 	
Release Detection (Subpart D)	<ul style="list-style-type: none"> • Must provide a method or combination of methods to detect leaks and releases from the UST system • Must comply with release detection requirements according to the schedule set forth in 40 CFR §280.40(c) 	

40 CFR PART 280 - UNDERGROUND STORAGE TANK REQUIREMENTS		
REQUIREMENTS	DESCRIPTION	AFFECTED FACILITY
<p>Release Reporting, Investigation, and Confirmation (Subpart E)</p> <p>Release Response and Corrective Action for UST Systems Containing Petroleum or Hazardous Substances (Subpart F)</p> <p>Out-of-Service UST Systems and Closure (Subpart G)</p>	<ul style="list-style-type: none"> • Petroleum USTs must comply with release detection requirements under 40 CFR §280.41 • Hazardous substance USTs must comply with release detection requirements under 40 CFR §280.42 • Must maintain records demonstrating compliance with release detection requirements • Must report any suspected releases within 24 hours or another reasonable time period specified by implementing agency • Must investigate and confirm any suspected releases • Must contain and cleanup any release, and report to implementing agency <p>In the event of a release</p> <ul style="list-style-type: none"> • Must notify implementing agency upon confirmation of a release and take action to prevent additional release • Must submit report to implementing agency that summarizes initial abatement activities within 20 days • Must submit site characterization report • Must develop and implement a corrective action plan as directed by implementing agency • For temporary closure, must maintain operating practices to ensure prevention of releases • Must notify within 30 days of permanent closure • Must maintain records to demonstrate compliance with closure requirements in accordance with §280.34 	<p>UST systems that manage petroleum or hazardous substances.</p>

40 CFR PART 280 - UNDERGROUND STORAGE TANK REQUIREMENTS		
REQUIREMENTS	DESCRIPTION	AFFECTED FACILITY
Financial Responsibility (Subpart H)	<ul style="list-style-type: none"> • Must demonstrate financial responsibility for taking corrective action and for compensating third parties for bodily injury and property damage caused by accidental releases 	

Emergency Planning and Community Right-to-Know Act (EPCRA)

The Emergency Planning and Community Right-To-Know Act (EPCRA), also known as Superfund Amendments Reauthorization Act (SARA) Title III, is designed to provide the general public and emergency planning and response personnel with information regarding the potential hazards in their community. EPCRA regulations identify emergency planning and notification procedures for hazardous chemicals in the community. Pursuant to EPCRA, EPA implements and enforces four regulatory programs applicable to pharmaceutical facilities. These programs are described below. The detailed requirements included in the applicable regulations are presented later in this section.

Hazardous Substance Notification

Pursuant to 40 CFR §302.6, facilities that release a hazardous substance in a quantity equal to or exceeding the reportable quantity (RQ) established in 40 CFR §302.4 must immediately notify the National Response Center at (800) 424-8802 and in the Washington, D.C. area at (202) 426-2675. Depending on the hazardous substance, the RQ ranges from 1 to 5,000 pounds. For this regulation, "release" means any spilling, leaking, pumping, emitting, emptying, discharging, injecting, escaping, leaching, dumping, or disposing into the environment, but excludes any release that results in exposure to persons solely within a workplace. Reporting procedures are similar to those required under 40 CFR Part 117 (CWA), but specify a different list of hazardous substances.

Emergency Planning and Notification

Pursuant to 40 CFR Part 355, any facility at which there is present an amount of any extremely hazardous substance, as defined in 40 CFR Part 355, equal to or in excess of its threshold planning quantity, shall notify the Commission (i.e., the State emergency response commission (SERC) or the Governor if there is no commission) and the local emergency planning committee (LEPC) identified in 40 CFR §355.30. Any facility producing, using, or storing a hazardous chemical, as defined in 40 CFR §355.20,

Emergency Planning and Community Right-to-Know Act

Hazardous Substance Notification	EPCRA-1
Emergency Planning and Notification	EPCRA-1
Hazardous Chemical Reporting: Community Right-to-Know	EPCRA-2
Toxic Chemical Release Inventory	EPCRA-2
EPCRA Assessment Considerations	EPCRA-3
EPCRA Regulatory Requirements	EPCRA-4

that releases an RQ of an extremely hazardous substance or a CERCLA hazardous substance must immediately notify the local emergency planning committee and the State emergency planning commission as specified in 40 CFR §355.40.

Hazardous Chemical Reporting: Community Right-To-Know

As required in 40 CFR Part 370, pharmaceutical facilities are required to submit a Material Safety Data Sheet (MSDS), as required in 29 CFR §1910.1200(c), or a list of hazardous chemicals for which MSDSs are required (i.e., a minimum threshold of zero pounds), for each hazardous chemical used as defined in 40 CFR §370.2 to the SERC, LEPC, and the fire department.

All pharmaceutical facilities must also submit a Tier I or Tier II Form, as identified in 40 CFR §§370.40 and 41, for all hazardous chemicals (above a threshold of 500 pounds) and all extremely hazardous chemicals (above a threshold of zero pounds) indicating the aggregate amount of these chemicals at their facilities classified by hazard category. All facilities must submit a Tier I form (Aggregate Information by Hazard Type). If any agency requests a Tier II report (Specific Information by Chemical), the pharmaceutical facility is required to submit this information within 30 days of the request. Any facility may submit a Tier II form in lieu of a Tier I form.

Information required in 40 CFR Part 370 must be submitted to the SERC, LEPC, and the fire department.

Toxic Chemical Release Inventory

Section 313 of EPCRA requires submission of the Toxic Chemical Release Inventory (TRI) Reporting Form (the Form R) as required in 40 CFR Part 372. Form R provides EPA with a compilation of release information that supports future regulations and also provides the public with information on releases of toxic chemicals in the community. Facilities subject to the requirement must report the quantities of both routine and accidental releases of listed toxic chemicals (40 CFR §372.65), the maximum amount of the listed toxic chemicals onsite during the calendar year, and the amount contained in wastes transferred offsite.

A complete Form R is required annually for each toxic chemical manufactured, processed, or otherwise used at each covered facility as described in 40 CFR Part 372. The form must be filed on or before July 1 of the following year and submitted both to EPA and the State.

Included in the Form R reporting requirements are air releases that are not released through any point source (stocks, vents, ducts, pipes, or any other combined air stream). These releases include (1) fugitive equipment leaks from valves, pump seals, flanges, compressors, sampling connections, etc.; (2) evaporative losses from surface impoundments and spills; (3)

releases from building ventilation systems; and (4) any other fugitive or non-point air emissions. Engineering estimates and mass balance equations may be useful in estimating these fugitive emissions.

Pharmaceutical manufacturing facilities that have 10 or more employees are required to submit a form for any Section 313 listed toxic chemical that is manufactured or processed at the facility in excess of a 25,000 pound threshold during the course of a calendar year or is a listed toxic chemical that is otherwise used at the facility in excess of a 10,000 pound threshold during the course of the year. (Toxic chemicals contained in mixtures and trade name products must also be accounted for when making threshold and release determinations.) The facility should use the best information available to determine chemical quantities. Section 313 listed toxic chemicals do not have to be considered if they are present in a mixture at less than a de minimis total of 1.0 percent, or 0.1 percent combined for toxic chemicals meeting the OSHA carcinogen standard. Uses that are exempt from reporting requirements include, among others, use of toxic chemicals contained in intake water (used for processing or non-contact cooling) or in intake air (used either as compressed air or for combustion).

A supplier notification requirement exists at 40 CFR Part 372, Subpart C for facilities that manufacture, import, or process a listed toxic chemical, and then sell or otherwise distribute a mixture or trade name product containing the toxic chemical above de minimis levels to either another manufacturing facility or another facility that then sells the same mixture or trade name product to another manufacturing facility. Supplier notification is also required if a waste mixture containing a toxic chemical is sold to a recycling or recovery facility. This notification must be made to each customer with the first shipment of each calendar year. Records of notifications must be kept for at least 3 years.

An alternative threshold of one million pounds per year applies to facilities that calculate the annual reportable amount of a toxic chemical to be less than 500 pounds for the combined total of quantities released, disposed, treated, recovered, combusted, and transferred. Facilities meeting these alternative reporting thresholds are not required to submit Form R for these chemicals. Rather, the regulations at 40 CFR §372.95 identify certification procedures that are to be followed.

EPCRA Assessment Considerations

When attempting to determine compliance with EPCRA at a pharmaceutical facility, activities will focus primarily on reporting and recordkeeping. The Form R is the highest profile reporting requirement under EPCRA. If the pharmaceutical facility meets the requirements set out above for reporting, it must submit a Form R annually for every chemical it has on site in excess of the threshold amounts. The Form R does not require specific studies or analyses, the information submitted may be based on existing information and on estimates.

However, EPA does consider data quality when reviewing the Form R and will question numbers and data that do not appear to be reasonable.

The facility should pay particular attention to intermediate products it manufactures and then uses in different products; it should also identify any chemicals it uses in waste treatment. The facility is required to submit a Form R both for intermediates and treatment chemicals. A facility should also be mindful of areas that are likely to have unreported spills, such as raw materials handling areas, pumps, and pipe fittings and connections. In addition, a facility should identify if (and where) volatile organic chemicals are used. VOC emissions in an open area to the atmosphere do constitute a regulated release under EPCRA. These emissions must be reported on the Form R.

EPCRA Regulatory Requirements

The following sections provide a summary of the principal regulations developed pursuant to EPCRA that may apply to the pharmaceutical industry. The regulations included are:

- ▶ **40 CFR Part 302 - Designation, Reportable Quantities and Notification**
- ▶ **40 CFR Part 355 - Emergency Planning and Notification**
- ▶ **40 CFR Part 370 - Hazardous Chemical Reporting, Community Right-to-Know**
- ▶ **40 CFR Part 372 - Toxic Chemical Release Reporting, Community Right-to-Know**

40 CFR Part 302

Designation, Reportable Quantities, and Notification

Designation of Hazardous Substances, §302.4

REQUIREMENTS	REGULATORY THRESHOLD
<p>Under Section 102(a) of CERCLA, these regulations identify reportable quantities of hazardous substances and set forth reporting requirements of releases.</p> <p>Listed hazardous substances are in Table §302.4 and are designated as “hazardous under Section 102 (a) of CERCLA.” Also included are “unlisted” hazardous substances which are defined in 40 CFR 302.4(b) as characteristics of hazardous waste.</p>	<p>The Table includes the reportable quantities of these substances. Unlisted hazardous substances have reportable quantity limit of 100 pounds (§302.5), except for unlisted hazardous wastes that exhibit extraction procedure (EP) toxicity as identified in Part 261 which vary based on the reportable quantity of the pollutant of concern and its lowest value in Table §302.4. Appendix A of §302.4 contains a sequential CAS number listing of chemicals and Appendix B contains a listing of regulated radionuclides.</p>

Notification Requirements, §302.6

REQUIREMENTS	REGULATORY THRESHOLD
<p>Facilities which release reportable quantities established in Table §302.4 must immediately notify the National Response Center at (800) 424-8802 or in the Washington D.C. area at (202) 426-2675.</p> <p>Table §302.4 is used to determine whether the regulations apply to a specific facility based on chemicals that are released.</p>	<p>Exposure to persons within a workplace is excluded. Reportable quantities range from 1 to 5,000 pounds. Release means any spill, leak, pumping, emitting, emptying, discharging, injecting, escaping, leaching, dumping, or disposing into the environment. Specific requirements for various types of radionuclides, including those which are exempt from reporting to the National Response Center are given in §302.6.</p>

40 CFR Part 355 Emergency Planning and Notification

Emergency Planning, §355.30

REQUIREMENTS	REGULATORY THRESHOLD
<p>Facilities subject to emergency planning requirements must notify the local and State emergency planning commissions. They must designate an emergency planning coordinator, provide information to the local planning committee, and calculate Threshold Planning Quantities [§355.30(e)] for substances listed in Appendices A and B of §355.</p> <ul style="list-style-type: none"> • §355.30(b) notification of planning commission due May 17, 1987, or within 60 days of becoming subject to the planning requirements; • §355.30(c) facility emergency coordinator designated due September 17, 1987, or 30 days after establishing a local emergency planning committee; • §355.30(d) information for planning must be provided “promptly” upon request. 	<p>The facility has onsite an extremely hazardous substance equal to or greater than its threshold planning quantity.</p>

Emergency Release Notification, §355.40

REQUIREMENTS	REGULATORY THRESHOLD
<p>A facility must immediately notify the local community emergency coordinator (or emergency response personnel) and State coordinator of reportable releases that will likely affect the local area or state. Notice must include chemical name or identity of any substance released, indication of whether it is an extremely hazardous substance, estimate of quantity released, estimate of time and duration of release, media into which release occurred, known or expected acute or chronic health risks including medical advice for exposed individuals, precautions to be taken, contact/phone numbers for further information.</p> <p>A written follow up emergency notice must be provided to update the information about the release, and actions taken. For transportation-related releases, this information can be provided to the 911 operator.</p>	<p>The facility produces, uses, or stores a hazardous chemical and there is a release of a reportable quantity of any extremely hazardous substance or CERCLA hazardous substance.</p>

General Applicability:

Any facility that is required to prepare or have available an MSDS for a hazardous chemical under OSHA (1970).

40 CFR Part 370

Hazardous Chemical Reporting: Community Right-to-Know (EPCRA)

Reporting Requirements, §370.20

This part applies to any amount of onsite hazardous chemicals greater than or equal to 10,000 lb and for all extremely hazardous substances present in an amount greater than or equal to 500 pounds, or the Threshold Planning Quantity (TPQ), whichever is less. Applicable facilities must submit Tier I forms by March 1, 1991, and annually thereafter. If requested, they must also submit Tier II forms.

MSDS Reporting, §370.21

Applicable facilities must submit to the local emergency planning committee, state emergency response commission and the local fire department (1) MSDSs for the facility for hazardous chemicals as required in §370.20; or (2) similar information including a list of hazardous chemicals by hazard category, the chemical or common name and components.

Reporting Upon Request, §370.21(d)

An MSDS must be provided for any changed chemicals within 3 months of the change.

Inventory Reporting, §370.25

The owner or operator must provide an inventory form to the emergency planning commission, the committee and the fire department with jurisdiction over the facility. It should contain Tier I information on hazardous chemicals present at the facility during the preceding calendar year above the threshold levels in §370.20(b). It must be submitted before March 1 each year. Tier II information may be submitted as an alternative per §370.25(b).

Submission of Tier II Information, §370.25(c)

Upon request by the SERC, LEPC, or local fire department, the facility must submit Tier II information.

Fire Department Inspection, §370.25(d)

The facility must allow the fire department to conduct inspections and must provide specific information on locations of hazardous chemicals upon request.

Mixtures, §370.28

Special reporting requirements apply for mixtures, including quantifying mixtures using procedures in §370.28.

Public Access and Availability of Information (Subpart C), §370.30

The committee must provide any person with MSDS or Tier II information for a specific facility, except upon request by the facility owner or operator, the commission or committee can withhold information on the locations of chemicals identified on Tier II forms.

Inventory Forms, Tier I and Tier II (Subpart D), §370.40

The forms contain information on hazardous and extremely hazardous chemicals onsite at the facility.

40 CFR Part 372
Toxic Chemical Release Reporting
Community Right-to-Know

Reporting Requirements, Subpart B

REQUIREMENTS	AFFECTED FACILITY
<p>This section of the regulations sets forth requirements for the submission of information relating to the release of toxic chemicals under §313 of EPCRA yearly on July 1. Date of applicability: February 16, 1988.</p>	<p>Section §372.22 specifies the types of facilities that are subject to the Form R reporting requirements:</p> <ul style="list-style-type: none"> a) facilities with 10 or more full time employees; b) facilities in SIC codes 20-39 (as of January 1, 1987). Criteria for the determination of SIC are further explained in Section §372.22(b); and (c) facilities which process, manufacture, or use a toxic chemical in excess of the threshold quantity set forth for the chemical in §§372.25 or 372.27. <p>Exemptions to the reporting of releases of toxic chemicals are detailed in §372.38 (e.g., de minimis concentrations, toxic chemicals contained in articles, structural components, routine janitorial uses, personal use by employees, maintaining motor vehicles, chemicals in process water or noncontact cooling water, and laboratory activities). Owners of industrial parks or similar real estate owners are also exempt since the operators of the facilities would hold this responsibility.</p>

Record Keeping, §372.10

REQUIREMENTS	REGULATORY THRESHOLD
Facilities must retain copies of reports, supporting documentation, including such items as data to show how reportable quantities were determined, data to calculate the quantity of a release, documentation of offsite transfer or release of toxic chemicals, and manifests or records for offsite transfer for a period of 3 years after each report is made. The reports must be available for inspection by EPA.	<p>All facilities subject to any reporting requirements in Part 372.</p> <p>Threshold in §372.25(a) applies to chemicals manufactured, imported or processed at a facility. The threshold is 25,000 lb/yr for chemicals manufactured or processed and 10,000 lb/yr for chemicals used.</p>

Reporting Requirements and Schedule for Reporting, §372.30

REQUIREMENTS	REGULATORY THRESHOLD
EPA Form 9350-1 (i.e. EPA Form R) is to be used to report chemicals above thresholds for manufactured, imported, processed, used or combined into a mixture or trade name product. Details on characterizing mixtures and trade name products are given in §372.30(b). Reports are due annually on July 1.	A regulated facility may consist of more than one establishment (defined as economic unit) and separate forms may be used for each establishment as long as reporting is accomplished for the entire facility.

Supplier Notification Requirement - Subpart C

REQUIREMENTS	REGULATORY THRESHOLD
<p>Facilities must notify the person to whom toxic chemicals, mixtures or trade name products containing toxic chemicals, are sold. The notification must be in writing and include specific information per §372.45(b): product trade name, a statement that the product contains a SARA Title III, Section 313 chemical and the chemical name, the CAS number of the chemical, and the percent by weight of each toxic chemical in the mixture or product.</p> <p>Notification must be with the first shipment of the product in each calendar year. If the product is renamed or changed, the notification must be initiated over again.</p>	<p>Owners and operators of facilities classified as SIC code 20-39 who manufacture, import or process toxic chemicals, and who sell or otherwise distribute a mixture or trade name product containing a toxic chemical to a facility who uses or sells the product or mixture. If an MSDS is required in accordance with 29 CFR 1910.1200, the notification must be attached or incorporated into the MSDS.</p> <p>Exceptions include mixtures or trade name chemicals with de minimis amounts (see §372.45(d) for others). However, if the chemical is considered proprietary (trade secret) under 29 CFR 1910.1200, the notification can be written with generic language.</p>

Specific Toxic Chemical Listings - Subpart D

Tables, with alphabetical and CAS number listings of chemicals and chemical categories, along with the effective date of the regulation for each of the chemicals are provided in §372.65.

Forms and Instruction - Subpart E Toxic Chemical Release Reporting Form and Instruction - §372.85

REQUIREMENTS	REGULATORY THRESHOLD
EPA Form R must be used and is available by writing to the Section 313 Document Distribution Center, PO Box 12505, Cincinnati, OH 45212.	Toxic chemicals, manufactured, processed, or otherwise used in excess of an applicable threshold in §372.25.

Clean Water Act (CWA) Regulatory Requirements

The primary objective of the Clean Water Act (CWA) is to restore and maintain the chemical, physical, and biological integrity of the nation's waters. The CWA regulates both "direct" discharges to waters of the United States and "indirect" discharges to publicly owned treatment works (POTWs). Under the authority of the CWA, several types of regulations have been developed to control discharges to the Nation's waters. Exhibit CWA-1 illustrates how the following regulations and permits work to limit the wastewater discharged:

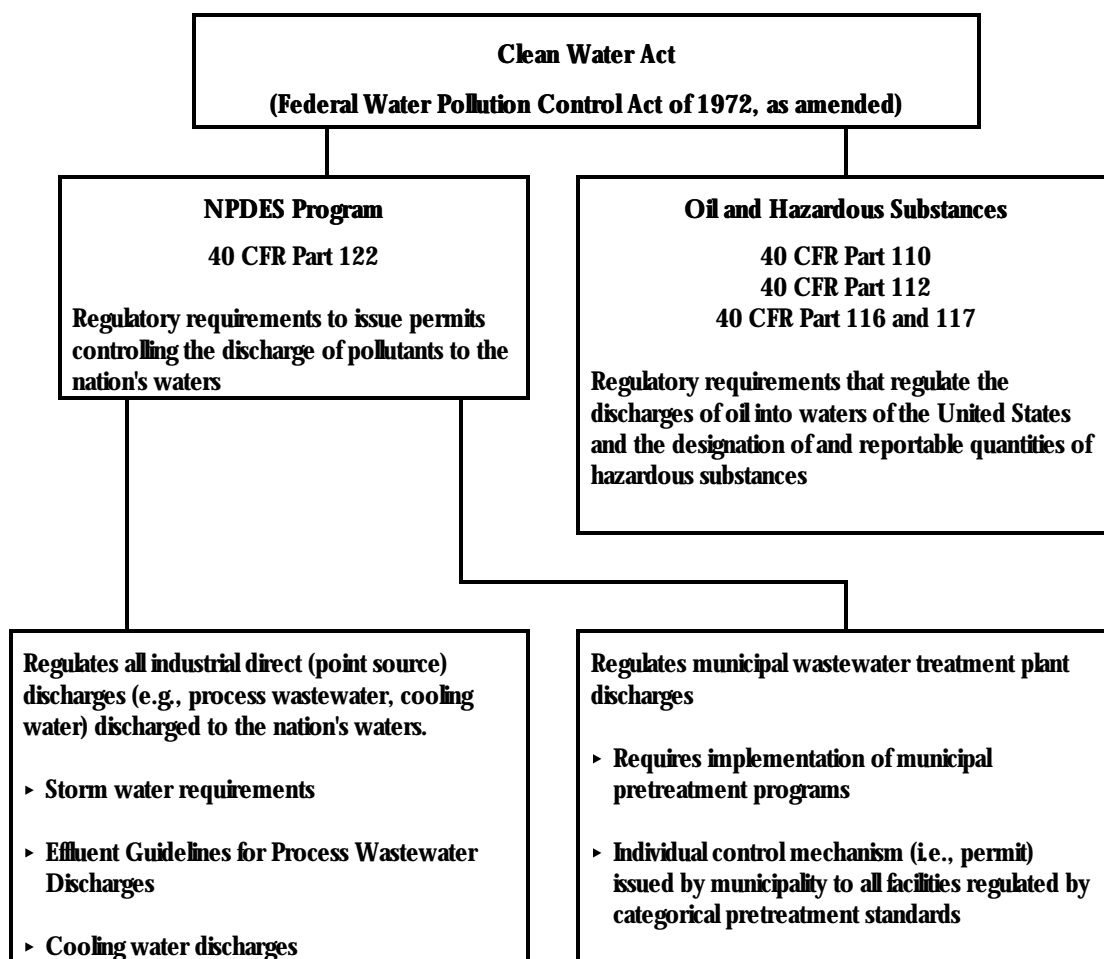
- ▶ **Effluent Limitation Guidelines and Categorical Pretreatment Standards** establishes limitations for direct and indirect discharges (40 CFR Part 405-471)
- ▶ **National Pollutant Discharge Elimination System (NPDES) Program** controls direct discharges (40 CFR Parts 122-125, 501, 503)
- ▶ **National Pretreatment Program** controls indirect discharges (40 CFR Parts 403)
- ▶ **Spills of Oil and Hazardous Substances [CWA §311(b)(3)]** prohibits oil discharges (40 CFR Part 110)
- ▶ **Oil Pollution Prevention** establishes procedures to prevent discharge of oil (40 CFR Part 112)
- ▶ **Reportable Quantities for Hazardous Substances** designates hazardous substances and the reportable volumes for each (40 CFR Parts 116 and 117).

The following sections address each regulation individually and identify the inspection considerations for programs implemented under the CWA. The following sections emphasize how the program is implemented with the specific requirements and compliance dates.

Clean Water Act

Effluents Limitations Guidelines and Categorical Pretreatment Standards	CWA-2
NPDES Program	CWA-4
Pretreatment Program	CWA-8
Policy on Effluent Trading in Watersheds	CWA-9
Spills of Oil and Hazardous Substances	CWA-10
Oil Pollution Prevention	CWA-10
Reportable Quantities for Hazardous Substances	CWA-11
CWA Assessment Considerations	CWA-11
CWA Regulatory Requirements	CWA-12

Exhibit CWA-1. CWA and Regulatory Requirements for Pharmaceutical Facilities



Effluent Limitations Guidelines and Categorical Pretreatment Standards

For the CWA, industrial wastewater is regulated either by effluent limitations guidelines (direct dischargers) or categorical pretreatment standards (indirect dischargers). Effluent guidelines and categorical pretreatment standards apply only to industrial users with specific industrial processes. Categorical pretreatment standards are technology-based limitations, requiring compliance at the end-of-process. EPA has promulgated effluent guidelines (for direct discharges) and existing source and new source pretreatment standards (for indirect dischargers) for over 30 industrial categories, including Pharmaceutical Manufacturing (Part 439).

In most cases, the pharmaceutical facility will have a wastewater discharge permit issued either by an EPA Regional office, the State, or the local sewer authority that incorporates applicable guidelines and standards. Where a facility discharges to a POTW that is not authorized to implement and enforce the pretreatment program, the facility will generally not

have a wastewater discharge permit unless it has been issued by the State. In these instances, it is the facility's responsibility to comply with the applicable categorical pretreatment standards and requirements. Specific applicability determinations are described in the appropriate regulation and are summarized below.

Process wastewater flows are defined in the regulations (40 CFR §401.11) to include waste waters resulting from manufacture of pharmaceutical products that come in direct contact with raw materials, intermediate products, or final products, and surface runoff from the immediate process area that has the potential to become contaminated. Non-contact cooling waters, utility waste waters, general site runoff, ground waters, and other nonprocess waste waters generated onsite are specifically excluded from the definition of process wastewater discharges. As such, the composition of each waste stream that is being generated is not as crucial as the amount of process and non-process wastewater, respectively.

Pharmaceutical Manufacturing

The existing Pharmaceutical Manufacturing regulations at 40 CFR Part 439 set effluent limitation guidelines (for direct dischargers) based on required removal efficiencies for BOD, COD, and TSS. In addition, the regulations specify cyanide limits according to the applicable Subpart (except Subpart E - Research for which categorical pretreatment standards are not specified) and set allowable pH ranges. Cyanide effluent limitation guidelines are not specified for discharges from bench-scale pharmaceutical research operations and product development activities under Subpart E. The existing regulations specify categorical pretreatment standards (for indirect dischargers) for cyanide only.

On May 2, 1995, EPA proposed revisions to the Pharmaceutical Manufacturing regulations. The proposed regulations set end-of-pipe effluent limitation guidelines (for direct dischargers) for BOD, COD, TSS, pH, and the priority and nonconventional pollutants contained in the applicable Subpart. EPA anticipates the rule to be finalized in early 1998. EPA may regulate Air Pollutants (NESHAPs) for the pharmaceutical industry.

Centralized Waste Treatment

On April 27, 1995, EPA proposed 40 CFR Part 437, Effluent Limitations Guidelines, Pretreatment Standards, and New Source Performance Standards: Centralized Waste Treatment Category (60 FR 5463). This proposed regulation would establish technology-based limits and standards for discharges by existing and new "centralized waste treatment facilities." The facilities covered by the guideline include stand-alone waste treatment and recovery facilities which treat waste received from offsite and also include treatment systems which treat onsite generated process wastewater with wastes received from offsite. Specifically, centralized waste treatment facilities include the following: (1) commercial facilities that accept waste from offsite for treatment from facilities not under the same ownership; (2) non-commercial facilities that accept waste from offsite for treatment only from facilities under the same ownership (i.e., intra-company transfer); or (3) mixed commercial/non-commercial facilities that accept some waste from offsite for treatment from

facilities not under the same ownership and some waste from facilities under the same ownership.

Pharmaceutical manufacturing facilities that might be covered by this rule should review the proposed regulation and note any future rulemaking activities for 40 CFR Part 437.

NPDES Program

NPDES permits, issued by either EPA or an authorized State (EPA has authorized 41 States and territories, as identified in Exhibit CWA-2, to issue permits), contain industry-specific technology-based (i.e., effluent guidelines as discussed in the previous section) and water quality-based effluent discharge limitations, as well as monitoring, record keeping, reporting, and other requirements. *All facilities discharging to the Nation's waters must receive an NPDES permit prior to initiating their discharges.*

This covers both process and non-process (e.g., non-contact cooling) waste waters, and storm water discharges associated with industrial activity that discharge either to a municipal separate storm sewer or directly to waters of the United States. To regulate such dischargers, EPA/States may issue NPDES permits to pharmaceutical facilities that include process, non-process, and storm water conditions or these may be in separate permits.

The NPDES permit program is implemented according to 40 CFR Part 122: EPA Administered Permit Programs: The National Pollutant Discharge Elimination System. These regulations establish the general program requirements, permit application requirements, permit conditions, and procedures for transfer, modification, revocation, reissuance, and termination of permits.

EPA issues two types of NPDES permits, individual and general. An individual permit is a permit tailored for a specific facility. A general permit regulates a category of similar dischargers within a geographical area or within a State. There are few exemptions to the requirement to obtain an NPDES permit, as specified in 40 CFR §122.3. For pharmaceutical facilities, there are four instances where this exemption may apply:

The terms process, non-contact cooling water, and industrial activity (as it applies to the storm water regulations) are defined in 40 CFR 401.11(q), 401.11(n), and 122.44(b) respectively.

- ▶ Discharges to POTWs (these discharges will be regulated by a permit issued by the POTW if the municipality has an approved pretreatment program and are regulated by the National Pretreatment Program)
- ▶ Discharges into privately owned treatment works, except as otherwise required by EPA
- ▶ Discharges of dredged or fill material (regulated by CWA §404)

Exhibit CWA-2. State NPDES Program Approval Status

State	Approved State NPDES Permit Program	Approved to Regulate Federal Facilities	Approved State Pretreatment Program	Approved General Permits Program
Alabama	10/19/79	10/19/79	10/19/79	06/26/91
Arkansas	11/01/86	11/01/86	11/01/86	11/01/86
California	05/14/73	05/05/78	09/22/89	09/22/89
Colorado	03/27/75	--	--	03/04/83
Connecticut	09/26/73	01/09/89	06/03/81	03/10/92
Delaware	04/01/74	--	--	10/23/92
Florida	05/01/95	--	05/01/95	05/01/95*
Georgia	06/28/74	12/08/80	03/12/81	01/28/91
Hawaii	11/28/74	06/01/79	08/12/83	09/30/91
Illinois	10/23/77	09/20/79	--	01/04/84
Indiana	01/01/75	12/09/78	--	04/02/91
Iowa	08/10/78	08/10/78	06/03/81	08/12/92
Kansas	06/28/74	08/28/85	--	11/24/93
Kentucky	09/30/83	09/30/83	09/30/83	09/30/83
Maryland	09/05/74	11/10/87	09/30/85	09/30/91
Michigan	10/17/73	12/09/78	04/16/85	11/29/93
Minnesota	06/30/74	12/09/78	07/16/79	12/15/87
Mississippi	05/01/74	01/28/83	05/13/82	09/27/91
Missouri	10/30/74	06/26/79	06/03/81	12/12/85
Montana	06/10/74	06/23/81	--	04/29/83
Nebraska	06/12/74	11/02/79	09/07/84	07/20/89
Nevada	09/19/75	08/31/78	--	07/27/92
New Jersey	04/13/82	04/13/82	04/13/82	04/13/82
New York	10/28/75	06/13/80	--	10/15/92
North Carolina	10/19/75	09/28/84	06/14/82	09/06/91
North Dakota	06/13/75	01/22/90	--	01/22/90
Ohio	03/11/74	01/28/83	07/27/83	08/17/92
Oregon	09/26/73	03/02/79	03/12/81	02/23/82
Pennsylvania	06/30/78	06/30/78	--	08/02/91
Rhode Island	09/17/84	09/17/84	09/17/84	09/17/84
South Carolina	06/10/75	09/26/80	04/09/82	09/03/92
South Dakota	12/30/93	12/30/93	12/30/93	12/30/93
Tennessee	12/28/77	09/30/86	08/10/83	04/18/91
Utah	07/07/87	07/07/87	07/07/87	07/07/87
Vermont	03/11/74	--	03/16/82	08/26/93
Virgin Islands	06/30/76	--	--	--
Virginia	03/30/75	02/09/82	04/14/89	05/20/91
Washington	11/14/73	--	09/30/86	09/26/89
West Virginia	05/10/82	05/10/82	05/10/82	05/10/82
Wisconsin	02/04/74	11/26/79	12/24/80	12/19/86
Wyoming	01/30/75	05/18/81	--	09/24/91
TOTALS	41	35	29	40

Number of Fully Authorized Programs (Federal Facilities, Pretreatment, General Permits) = 26

* New with phased Federal facilities & storm water programs by 2000.

- ▶ **Any discharge in compliance with instructions from an on-scene coordinator pursuant to 40 CFR Part 300 (i.e., The National Oil and Hazardous Substances Pollution Contingency Plan) or 33 CFR §153.10(e) (i.e., Pollution by Oil and Hazardous Substances).**

[Note: Pollution by Oil and Hazardous Substances is enforced by the Coast Guard and is not discussed herein.]

EPA or the State may terminate or modify a permit where it is determined that a permitted activity endangers human health or the environment and can only be regulated to acceptable levels by a permit modification or termination of the permit. Likewise, the permit may be terminated or an application denied if the permittee fails to fully disclose all relevant facts or misrepresents relevant facts at any time. EPA or the State may modify a permit as a minor modification allowing for a change in

ownership or operational control of a facility where the Director determines that no other change in the permit is necessary, provided that a written agreement containing a specific date for transfer of permit responsibility, coverage, and liability between the current and new permittee has been submitted to the Director as specified in 40 CFR §122.61.

Specific permit applicability requirements for storm water discharges are identified in 40 CFR §122.26(a). Facilities requesting to be covered under the storm water general permitting program are required to submit a Notice of Intent (NOI) to be covered under the general permit consistent with 40 CFR §122.28.

The evaluation team should be aware that NPDES permits are issued with both an issuance and expiration date and the permits are issued for a period of up to 5 years. In some instances, the NPDES permits issued by EPA or the State remain in effect even after their expiration date, provided that the facility has submitted a timely and complete application (pursuant to 40 CFR §122.21) and EPA or the State, through no fault of the permittee, does not issue a new permit with an effective date on or before the expiration date of the previous permit.

Pursuant to 40 CFR §122.21, new dischargers are required to apply at least 180 days before commencing discharge while existing permittees are required to reapply at least 180 days prior to the expiration date of the existing permit, unless a later date has been granted by the Director. In no case may an application be submitted after the expiration date of an existing permit. EPA has specific application forms that are to be used for NPDES permits.

Application forms that apply to a pharmaceutical facility include:

Form	Title	Regulation Cite
1	General Information	122.21(f)
2C	Existing manufacturers	122.21(g)
2D	New manufacturers	122.21(k)
2E	Manufacturers that only discharge non-process wastewater	122.21(h)
2F	Storm water discharges associated with industrial activity and consistent with the requirements of 122.26(c)	122.26(d)

While specific permit conditions might vary from permit to permit, all NPDES permits must contain the conditions specified in 40 CFR §122.41. In general, these include requirements for:

- ▶ **Reapplication**
- ▶ **Operation and maintenance**
- ▶ **Effluent limitations**
- ▶ **Monitoring and record keeping**
- ▶ **Reporting**
- ▶ **Bypass restrictions**
- ▶ **Upset provisions**
- ▶ **Other standard conditions.**

For pharmaceutical facilities, both maximum daily and average monthly discharge permit limitations are set for each regulated pollutant (i.e., technology-based limitations), water quality considerations, and the permit writer's best professional judgment.

All pharmaceutical manufacturing facilities are also required to notify the permitting authority as soon as they know or have reason to believe that any activity has occurred or will occur which would result in the discharge, on a routine, non-routine, frequent, or infrequent basis, of any toxic pollutant which is not limited in the permit, if that discharge will exceed the highest of specified notification levels as identified in 40 CFR §122.42(a).

Additionally, environmental laws (as identified in 40 CFR §122.49) may apply to the issuance of NPDES permits. Specific laws that may apply include:

- ▶ **Wild and Scenic Rivers Act**
- ▶ **National Historic Preservation Act of 1966**
- ▶ **Endangered Species Act**
- ▶ **Coastal Zone Management Act**
- ▶ **Fish and Wildlife Coordination Act**
- ▶ **National Environmental Policy Act.**

It is the facility's responsibility to work with the EPA State NPDES permit writers to ensure that these statutes are adequately addressed during the permitting process. The evaluation of applicability for each of these statutes will occur as part of permit development.

Pretreatment Program

The goals of the pretreatment program are to: (1) prevent damage to municipal wastewater treatment plants that may occur when hazardous, toxic or other wastes are discharged into a sewer system (i.e., interference); (2) prevent pollutants from passing through the treatment plant untreated and violating discharge limitations or causing exceedances of water quality standards; and (3) encourage the reuse and recycling of municipal and industrial sludge (i.e., protect the quality of sludge generated by these plants). Nationwide, approximately 1,500 POTWs have been required to develop and implement local municipal pretreatment programs. The requirement to develop and implement a program is included in the POTW's NPDES permit. Through this program, the POTW is directly responsible for regulation of certain significant industrial users discharging to the POTW wastewater treatment system, including facilities regulated by categorical pretreatment standards. EPA's General Pretreatment Regulations for Existing and New Sources of Pollution (40 CFR Part 403) establish requirements for POTW programs to regulate discharges from industrial facilities to POTWs and establishes certain requirements for industrial users (e.g., monitoring and record keeping).

In most instances, pharmaceutical facilities discharge to POTWs that are authorized to implement and enforce the pretreatment requirements through an approved pretreatment program. Where this occurs, the facility is required to abide by the terms of a POTW-issued control mechanism (e.g., permit) and the local sewer use ordinance (SUO). It is the POTW's responsibility to appropriately implement and enforce these requirements and its pretreatment program, that must be at least as stringent as the Federal pretreatment requirements specified in 40 CFR Part 403, on its industrial users. However, even if a POTW fails to properly apply Federal or State regulations, the pharmaceutical facility has an independent obligation to comply with applicable Federal and State requirements.

Some pharmaceutical facilities are located in municipalities that do not have locally-run pretreatment programs. In these areas, permits are generally not issued by EPA or the State; rather these facilities are obligated to comply with Federal and/or State pretreatment requirements as identified in the regulations. Both the general pretreatment regulations (40 CFR Part 403) and the pharmaceutical categorical pretreatment standards apply to the facility. Currently, EPA has delegated pretreatment program authority to 29 States (as identified in Exhibit CWA-2), in which the State directly controls those industries that discharge to municipalities without locally-run pretreatment programs. In all remaining States, unless the POTW is authorized to implement and enforce its own pretreatment program, EPA implements and enforces the program.

The 40 CFR Part 403 pretreatment regulations specify, among other things, requirements for non-domestic sources discharging pollutants into POTWs. The regulations set out three different types of effluent limitations for industrial discharges: prohibited discharge standards, categorical pretreatment standards, and local discharge limitations.

Prohibited discharge standards forbid certain types of discharges to the POTW, including POTWs without approved pretreatment programs. These standards include both general and specific prohibitions. The general prohibitions are national prohibitions against pollutants discharged to a POTW that cause pass through or interference, as defined in §403.3. Specific prohibitions, at 40 CFR §403.5(b), are national prohibitions against pollutants that cause problems at the POTW, such as fire or explosion, harm to worker health and safety, corrosion, obstruction of flow, excessive heat, trucked or hauled waste or excessive mineral or synthetic oil and grease.

As noted earlier effluent guidelines and categorical pretreatment standards apply to specific process water waste streams from specific industrial processes, including pharmaceutical manufacturing (40 CFR Part 439). The standards are technology-based and apply at the end of the regulated industrial process.

Since National prohibited discharge standards and categorical standards are not POTW-specific, these limitations may not necessarily protect a POTW from pass through or interference. As such, all POTWs authorized to implement and enforce a local pretreatment program, and many other POTWs that have received problematic discharges from their industrial users, are required to develop local discharge limitations to address site-specific concerns regarding interference with the POTW wastewater collection system or treatment plant or pass through of pollutants to the receiving stream or sludge. In addition, local limits translate prohibited discharge standards into numerical limitations that can be more readily evaluated.

The General Pretreatment Regulations (40 CFR Part 403) also specify reporting requirements applicable to industrial dischargers. POTWs may set more stringent requirements in their local sewer use ordinance or in a wastewater discharge permit issued to the pharmaceutical facility, but at a minimum, pharmaceutical facilities must submit semiannual monitoring reports (403.12(e)), notices of potential problems, including slug loads (403.12(f)), notification of effluent violations (403.12(g)(2)), notification of changed discharge (403.12(j)); must keep records as required (403.12(o)), and must notify of hazardous waste discharges (403.12(p)). The regulations also include upset and bypass provisions, in §403.16 and §403.17, respectively, that apply to industrial dischargers.

Policy on Effluent Trading in Watersheds

The evaluation team should be aware of EPA's draft Framework for Watershed-Based Effluent Trading (May 1996). The fundamental principle of trading within the Clean Water Act

framework is that water quality standards must be met and technology-based requirements must remain in place.

Trading is a method to attain and/or maintain water quality standards, by allowing sources of pollution to achieve pollutant reductions through substituting a cost-effective and enforceable mix of controls on other sources of discharge. Effluent trading potentially offers a number of economic, environmental, and social benefits. Proposed types of effluent trading approaches are (1) intra-plant, (2) pretreatment, (3) point/point source, (4) point/nonpoint source, and (5) nonpoint/nonpoint source.

Watershed-based trading will be implemented on a voluntary basis under existing CWA authorities. There will be a substantial public outreach effort to obtain stakeholders' (e.g., regulated sources, non-regulated sources, regulatory agencies, and the public) recommendations and insights on draft portions of the trading policy prior to implementation. Facilities interested in this trading policy should initiate dialogue with their local permitting authority.

Spills of Oil and Hazardous Substances

The regulations at 40 CFR Part 110 apply to the discharge of oil, which is prohibited by Section 311(b)(3) of the CWA. For purposes of this regulation, "discharge" is defined as any spilling, leaking, pumping, pouring, emitting, emptying, or dumping. Prohibited discharges include those into or upon the navigable waters of the United States, adjoining shorelines, or the contiguous zone or that which may affect natural resources under the jurisdiction of the United States in such quantities that may be harmful to the public health or welfare of the United States. EPA has determined that such harmful discharges of oil include those that violate applicable water quality standards, or cause a film or sheen upon or discoloration of the surface of the water or adjoining shorelines or cause a sludge or emulsion to be deposited beneath the surface of the water or upon adjoining shorelines. Addition of dispersants or emulsifiers to oil to be discharged that would circumvent these provisions is prohibited. The National Response Center as described in 40 CFR §110.10 must be immediately notified of any discharge in violation of these restrictions.

Oil Pollution Prevention

The regulations at 40 CFR Part 112 establish procedures, methods and equipment, and other requirements for equipment to prevent the discharge of oil into or upon the navigable waters of the United States or adjoining shorelines (i.e., preparation and implementation of Spill Prevention Control and Countermeasure (SPCC) Plans). This part applies to owners or operators of non-transportation related onshore and offshore facilities engaged in drilling, producing, gathering, storing, processing, refining, transferring, distributing, or consuming oil and oil products which could reasonably be expected to discharge oil in harmful quantities, as defined in 40 CFR Part 110. Standards for the preparation and implementation of a SPCC Plan are set out in 40 CFR §112.7, while specific requirements for these Plans are outlined in 40 CFR §112.3.

This Part does not apply to facilities that both (1) have an underground buried storage capacity for oil of 42,000 gallons of oil or less and (2) the storage capacity for oil, which is not buried, is 1,320 gallons or less, provided that no single container has a capacity in excess of 660 gallons.

Reportable Quantities for Hazardous Substances

Under Section 311(b) the Federal Water Pollution Control Act, EPA promulgated rules which designate hazardous substances and the reportable quantity (RQ) of hazardous substances, respectively (40 CFR Parts 116 and 117). When an amount equal to or in excess of the RQ is discharged into or upon the navigable waters of the United States, adjoining shorelines, or into or upon the contiguous zone, the facility must provide notice to the Federal government of the discharge, following Department of Transportation requirements set forth in 33 CFR §153.203. For purposes of this regulation, "discharge" means any spilling, leaking, pumping, pouring, emitting, emptying, or dumping. This requirement does not apply to facilities that discharge the substance in compliance with an NPDES permit or a Part 404 Wetlands (dredge and fill) permit. RQs for specific chemicals are listed in 40 CFR §117.3.

CWA Assessment Considerations

To evaluate compliance with effluent limitations and effluent monitoring, the assessor should verify that the facility's operations are properly regulated by the permit and that monitoring results are representative of the facility's operations. Pharmaceutical production may be either a batch or continuous operation. For batch processes, the amount and frequency of wastewater generated is potentially much higher than for continuous processes. The investigator should verify that facility operations have not changed such that wastewater characteristics changed significantly, but if so, that proper notification was given to the permitting authority.

The assessor team should pay particular attention to treatment system performance at a pharmaceutical facility. Where treatment systems are installed, the investigator needs to verify that proper O&M practices are in place to ensure consistent treatment plant performance. O&M should include documentation of all activities performed (e.g., calibrations, inspections, repairs, chemical additions, etc.). Evaluation of trends in monitoring results can indicate improper O&M. For example, steam strippers can lose efficiency due to fouling of the packing material if the equipment is not cleaned at the proper frequency. The investigator should verify that backup systems or procedures exist for the periods when system O&M is being conducted. Also, the investigator should verify that the facility has adequate staff to operate and maintain the treatment system. In many instances, this may require full-time, around the clock staffing.

Because of the vast array of process equipment and piping, it is important that the facility's operation and maintenance (O&M) program include regular facility assessments for leaks, spills, and stressed equipment and a documented procedure for conducting these assessments. In addition, areas that have a high potential for spills or leaks (e.g., pipes,

pumps, fittings, etc.) should have spill containment installed to prevent major releases to the environment, to the facility's onsite treatment system, or to the POTW.

Finally, when evaluating compliance with effluent limitations, the investigator should verify that the monitoring results are representative of facility operations and consistent with 40 CFR Part 136 procedures. [Note that "EPA approved methods" does not indicate that proper procedures were followed. EPA has approved methods for drinking water, wastewater, and solid waste which can all be used to analyze pollutant concentrations in wastewater, but only Part 136 regulations apply to CWA regulations.] Because of the potential variations in production at pharmaceutical facilities, a wastewater sample collected on a given day may not be a fair estimate of typical facility operations. Also, wastewater from pharmaceutical manufacturers can be highly complex, causing matrix interferences that can hinder laboratory analysis at the regulatory limitations. The assessor should verify that analytical results reported as "Not Detected" have been analyzed down to the requisite quantification level. In June 1993, EPA published a guidance manual on laboratory protocol to improve analytical performance due to matrix interference and other complications. The manual is called *Guidance on Evaluation, Resolution, and Documentation of Analytical Problems Associated with Compliance Monitoring*.

When evaluating compliance with the oil and hazardous substance regulations, the investigator should inquire about past instances of spills (or leaks, pumping, etc.) and should identify how the facility reacted to each circumstance. Specifically, the assessors should note: what material was spilled; where did the discharge go; what quantity was spilled; what was the reportable quantity; what was the facility's response for containment, clean-up, and notification; any related health and safety issues for the plant, the community, or the environment; and what are the facility's plans to prevent a recurrence of the situation. The assessor should also review the SPCC Plan and any other spill or slug control plan onsite applicable to the facility. As part of the pretreatment program, the facility may be required to implement a spill and slug control plan concurrent with the SPCC plan and reportable quantities regulation.

CWA Regulatory Requirements

The following section provides a summary of the principal regulations developed pursuant to the CWA that are applicable to the pharmaceutical industry. The regulations included are:

- ▶ **40 CFR Part 439 - Pharmaceutical Manufacturing**
- ▶ **40 CFR Part 110 - Discharge of Oil**
- ▶ **40 CFR Part 112 - Oil Pollution Prevention**
- ▶ **40 CFR Part 116 - Designation of Hazardous Substances**

- ▶ **40 CFR Part 117 - Determination of Reportable Quantities for Hazardous Substances**

The regulatory summaries for applicable effluent guidelines are provided for direct discharges (i.e., facilities that discharge directly to waters of the U.S. and are regulated by an NPDES permit) and those that discharge indirectly (i.e., discharge to a Publicly Owned Treatment Works (POTW) which in turn discharges to waters in the U.S.)

Applicability:

Any pharmaceutical manufacturing facility discharging process waste waters to water of the United States.

Exemptions:

- None

Applicable Subparts:

Subpart A: Fermentation Products

Subpart B: Extraction Products

Subpart C: Chemical Synthesis Products

Subpart D: Mixing, Compounding, and Formulating

Subpart E: Research

40 CFR Part 439

Pharmaceutical Manufacturing as Administered Through 40 CFR Part 122: EPA Administered Permits Programs, The National Pollutant Discharge Elimination System

40 CFR PART 439 - DIRECT DISCHARGES	
REQUIREMENTS	COMPLIANCE DATES
<p>Discharge Limitations:</p> <ul style="list-style-type: none">• Effluent limitations contained in 40 CFR Part 439 including:<ul style="list-style-type: none">- BOD, COD, and TSS limits based on required removal efficiencies (Subparts A, B, C, D, E)- Allowable pH range (Subparts A, B, C, D, E)- BPT, BAT and NSPS cyanide limits (Subparts A, B, C, D) <p>Relate to May 2, 1995, proposed rule:</p> <ul style="list-style-type: none">- BPT end-of-pipe limits for BOD, TSS, COD, and pH (Subparts A, B, C, D)- BPT, BAT, or NSPS cyanide limits at in-plant monitoring points (Subparts A,C)- BAT or NSPS end-of-pipe limits for priority and nonconventional pollutants (Subparts A, B, C, D)- BOD, COD and TSS limits based on required removal efficiencies and allowable pH range (Subpart E)	<p>Existing Sources: 10/27/86 (under current regulations as required by permit)</p> <p>New Sources: Date source begins operation, as required by permit</p> <p>Compliance with specific permit limitations upon effective date of the permit</p>

40 CFR PART 439 - DIRECT DISCHARGES	
REQUIREMENTS	COMPLIANCE DATES
<ul style="list-style-type: none"> Any other effluent limitation contained in the NPDES permit <p>Monitoring and Reporting Requirements:</p> <p>Note: All direct dischargers are required to obtain an NPDES permit. The NPDES permit outlines the dischargers specific monitoring and reporting requirements.</p> <ul style="list-style-type: none"> <u>Permit Applications</u> – containing the information required under 122.21(f), (g), and (k) (application requirements for new sources and new discharges) Permit applications are to be submitted 180 days prior to the commencement of discharge. Applications for permit renewal are required to be submitted 180 days before the existing permit expires. <u>Planned Changes</u> – notification to the Director as soon as possible of any planned physical alteration or addition that meets the criteria in 122.41(l)(1). As soon as possible, when applicable <u>Anticipated Noncompliance</u> – advance notification to the Director of any planned changes that may result in permit noncompliance <u>Monitoring Reports</u> – monitoring results must be submitted as required by the NPDES permit (at least annually). All monitoring must be conducted using 40 CFR Part 136 methods <p>Permittees not using or generating cyanide may certify in lieu of monitoring</p> <p>(Section 439.2 specifies required monitoring frequencies for each regulated pollutant generated or used at a facility.)</p> <ul style="list-style-type: none"> <u>Compliance Schedules</u> – reports of compliance or noncompliance with compliance schedule requirements <u>Anticipated and Unanticipated Bypass</u> – notification as required under 122.41(m) <u>Discharge of Toxic Pollutants</u> – notification to the Director of activity that results in the discharge of toxic pollutants not limited in the permit, if it exceeds the levels outlined in 122.42(a)(1) <u>Storm Water Permit Applications</u> – submission of either individuals permit application, group permit applications, or general permit applications 	<p>Permit applications are to be submitted 180 days prior to the commencement of discharge</p> <p>Applications for permit renewal are required to be submitted 180 days before the existing permit expires</p> <p>As soon as possible, when applicable</p> <p>In advance of changes, when needed</p> <p>At least annually or more frequently by permit</p> <p>Within 14 days of each compliance schedule date</p> <p>At least 10 days prior to anticipated bypass. Within 24 hours of unanticipated bypass</p> <p>As soon as facility knows or has reason to believe that levels will be exceeded</p>

40 CFR PART 439 - DIRECT DISCHARGES	
REQUIREMENTS	COMPLIANCE DATES
<ul style="list-style-type: none"> – Individual permit applications must include the information in 122.26(c)(1) – Group permit applications requirements are identified in 122.26(c)(2) – Facilities to be covered under a general permit must file a Notice of Intent (NOI) • <u>Other Storm Water Reports</u> – submission of other reports as required under a facility's storm water discharge permit. These reports may include pollution prevention plans and monitoring reports <p>Record Keeping Requirements:</p> <ul style="list-style-type: none"> • Records of monitoring information as required under 122.41(j) must be kept for at least three years 	<p>Individual permit applications for existing facilities were due October 1, 1992. New facilities must submit an application 180 days prior to commencement of industrial activity</p> <p>Part 1 applications were due on September 30, 1991, and Part 2 applications were due on October 1, 1992</p> <p>NOIs from existing facilities were due on October 1, 1992</p> <p>NOIs from new facilities are due 2 days prior to the commencement of industrial activities</p> <p>Due dates as required by permits</p>

Any pharmaceutical manufacturing facility discharging process wastewater to a POTW.

Pharmaceutical Manufacturing as Administered Through 40 CFR Part 403: General Pretreatment Regulations for Existing and New Sources of Pollution

40 CFR PART 439 - INDIRECT DISCHARGES	
REQUIREMENTS	COMPLIANCE DATES
<p>Discharge limitations:</p> <ul style="list-style-type: none"> • Limitations contained in 40 CFR Part 439 including: <ul style="list-style-type: none"> - Cyanide limits (Subparts A, B, C, D) <p>Relate to May 2, 1995, proposed rule:</p> <ul style="list-style-type: none"> - Priority and non-conventional pollutants limits at in-plant and end-of-pipe monitoring points (Subparts A, B, C, D) • Prohibited discharge standards (general and specific) in 40 CFR 403.5 • Applicable local limits <p>Monitoring and reporting requirements:</p> <p>Note: Reports must be submitted whether or not the facility has been issued a permit</p> <ul style="list-style-type: none"> • <u>Baseline Monitoring Reports (BMR)</u> – containing the information required under 40 CFR 403.12(b) • <u>Compliance Schedule Progress Reports</u> – containing the information required under 40 CFR 403.12(c)(3) 	<p>PSES: 10/27/86, as required by permit</p> <p>PSNS: Date new source begins operation as required by permit</p> <p>BMRs from existing sources due within 180 days of effective date of categorical pretreatment standard (June 9, 1984, for current regulations)</p> <p>BMRs from new sources are due 90 days prior to commencement of discharge</p> <p>Due within 14 days of completing compliance schedule milestone or due date</p>

40 CFR PART 439 - INDIRECT DISCHARGES	
REQUIREMENTS	COMPLIANCE DATES
<ul style="list-style-type: none"> <u>90-Day Compliance Report</u> – containing the information required under 40 CFR 403.12(d) <u>Periodic Reports on Continued Compliance</u> – containing the information in 403.12(e) (including monitoring data for all categorically regulated pollutants). All monitoring must be conducted using 40 CFR Part 136 methods. <p>Dischargers not using or generating cyanide may certify in lieu of monitoring.</p> <p>(Section 439.2 specifies required monitoring frequencies for each regulated pollutant generated or used at a facility.¹)</p> <ul style="list-style-type: none"> <u>Notice of Potential Problems Including Slug Loadings</u> <u>Notice of Changed Discharge</u> – advanced notification of any substantial change in the volume or character of pollutants in the discharge (including hazardous wastes) <u>Notice of Violations and Resampling</u> – notification due to the Control Authority within 24 hours of noting a violation; results of resampling must be submitted within 30 days <u>Notification of Hazardous Waste Discharge</u> – notification to the POTW, EPA, and the State of the hazardous wastes discharged to the POTW <p>Record keeping requirements:</p> <ul style="list-style-type: none"> Monitoring records including the information listed in 403.12(o) must be maintained for at least 3 years 	<p>Due within 90 days following date for final compliance (10/27/86 under current regulations) or for new sources following the commencement of introduction of wastewater to the POTW</p> <p>Must be submitted at least semiannually</p> <p>Due to the Control Authority immediately upon identification of discharges that could cause problems to the POTW</p> <p>Prompt notification in advance of any substantial change</p> <p>Notice within 24 hours, results of resampling within 30 days</p> <p>One time notification, unless changes to discharge</p>

Applicability:

Prohibited discharges include certain discharges to U.S.

Navigable water, to adjoining

shorelines, or to waters of the contiguous zone, occurring in connection with activities under the Outer Continental Shelf Lands Act or the Deepwater Port Act, or those that may affect U.S. natural resources.

40 CFR Part 110

Discharge of Oil

May be applicable to pharmaceutical facilities using oil and that are either located by a municipal storm sewer that discharges to waters or near streams or bodies of water.

40 CFR PART 110	
REQUIREMENTS	COMPLIANCE DATES
<ul style="list-style-type: none">• Discharge of oil is prohibited that:<ul style="list-style-type: none">– Violates applicable water quality standards, or– Causes a film or sheen upon or discoloration of the surface of the water or adjoining shorelines or causes a sludge or emulsion to be deposited beneath the surface of the water or upon the adjoining shorelines• Notification must be provided immediately to the National Response Center of any discharge of oil in violation of the prohibition at (800) 424-8802 or (202) 426-2675 in the Washington, DC, metropolitan area.	

Applicability:

Non-transportation related onshore and off-shore facilities engaged in drilling, producing,

gathering, storing, processing, refining, transferring, distributing, or consuming oil and oil products that could reasonably discharge oil in harmful quantities, as defined in Part 110.

40 CFR Part 112 **Oil Pollution Prevention**

Exemptions:

- Facilities with underground buried oil storage capacity of $\leq 42,000$ gallons; and
- Storage capacity that is not buried $\leq 1,320$ gallons, with no single container capacity > 660 gallons

40 CFR PART 112	
REQUIREMENTS	COMPLIANCE DATES
<p>Reporting requirements:</p> <ul style="list-style-type: none">• Prepare and implement Spill Prevention Control and Countermeasure plans meeting the requirements of 112.3 and 112.7• Submit report as described in 112.4 when discharged oil $> 1,000$ gallons in single spill event or discharged oil in harmful quantities in two spill events• Review, evaluate, and update plan as required under 112.5 <p>Certain non-transportation related onshore facilities which could reasonably be expected to cause substantial harm to the environment may also be required to implement the following provisions:</p> <ul style="list-style-type: none">• Submit facility response plan as described in 112.20 and develop and implement facility response training and drill exercise as described in 112.21	<p>Existing sources:</p> <p>New sources: Prepare plan within 6 months of beginning operation and fully implement in no later than 1 year</p> <p>Within 60 days of becoming subject to reporting requirements</p> <p>Review plan once every 3 years, amend plan within 6 months, if needed</p> <p>Existing sources: as described in 112.20 New source: prior to start of operations</p>

Applicability:

40 CFR Part 117 does not apply to facilities that discharge the substance under an NPDES permit or to a POTW, as long as any applicable effluent limit or pretreatment standard is met.

40 CFR Part 116 and 117
**Designation of Hazardous Substance and 40
CFR Part 117 Determination of Reportable
Quantities for Hazardous Substances**

Requirements:

40 CFR 116.4 designates hazardous substances and 40 CFR 117.3 establishes the Reportable Quantity (RQ) for each substance listed in Part 116. When an amount equal to or in excess of the RQ is discharged, the facility must provide notice to the Federal government following DOT requirements in 33 CFR 153.203.

